



EXHIBIT 87

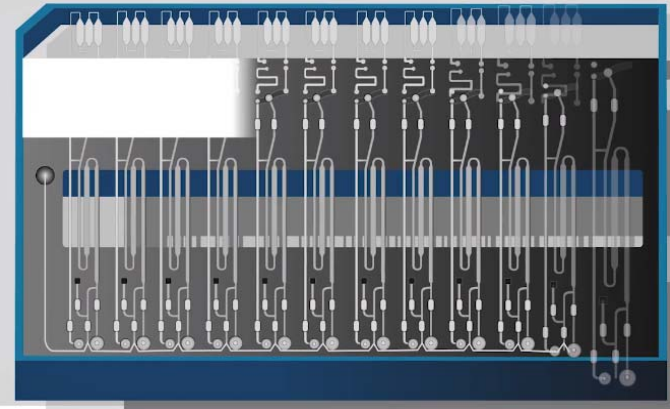
EXHIBIT 87

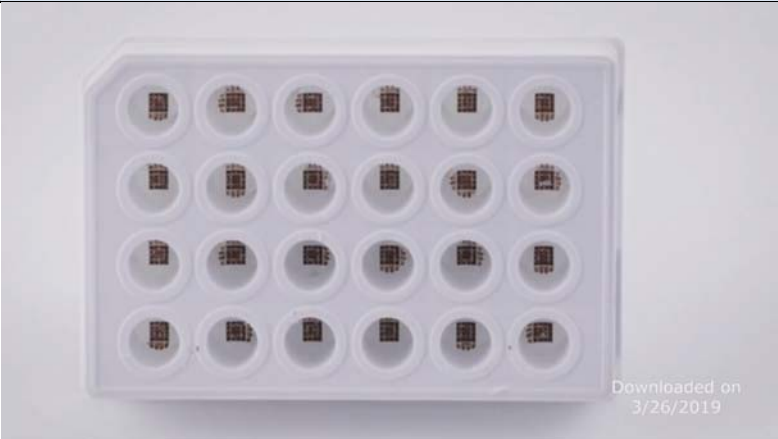
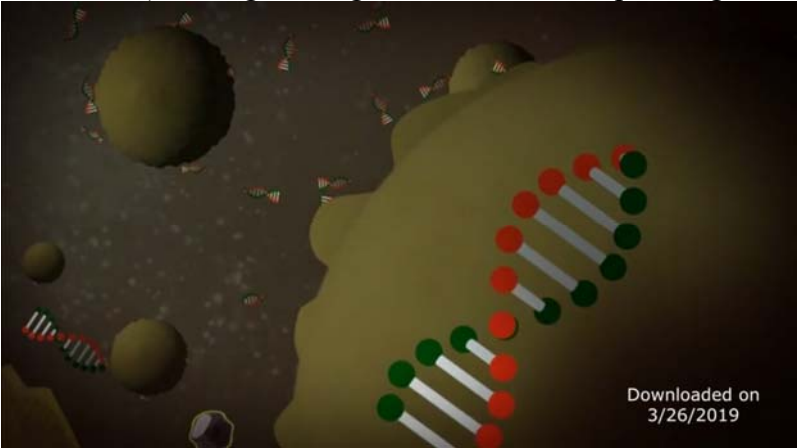
U.S. Patent No. 10,443,088 Infringement Chart

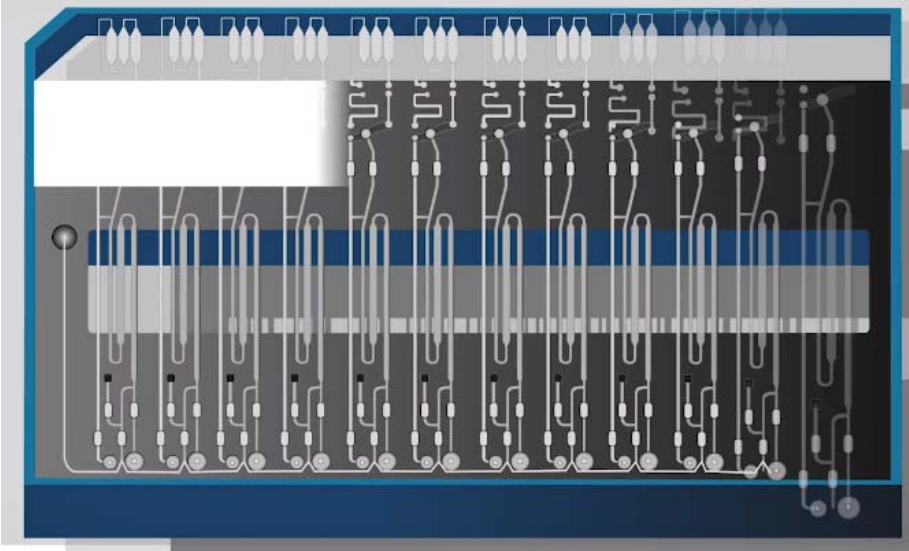
Claim	Claim Language	Infringement Evidence
1(a)	A method for processing a polynucleotide-containing sample, the method comprising:	<p>To the extent the preamble is limiting, the accused workflow comprises processing a polynucleotide-containing sample.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-products/, last visited June 5, 2019 (Exhibit 12)</p> <div></div> <p><i>NeuMoDx™ Molecular Systems</i>, NeuMoDx, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul style="list-style-type: none">“NeuMoDx™ Molecular Systems provide the industry’s first true continuous random-access solution and is scalable to meet the needs of the modern clinical laboratory. The ability to load samples and testing consumables on the fly offers up to 8 hours of operator walkaway capability. Room temperature stable reagents and consumables dramatically reduce waste resulting in unmatched flexibility. Liquid handling and transport is achieved through proven robotic technologies. Our proprietary and unitized microfluidic cartridge features independent lanes allowing for simultaneous processing of sample types and varying assays.”


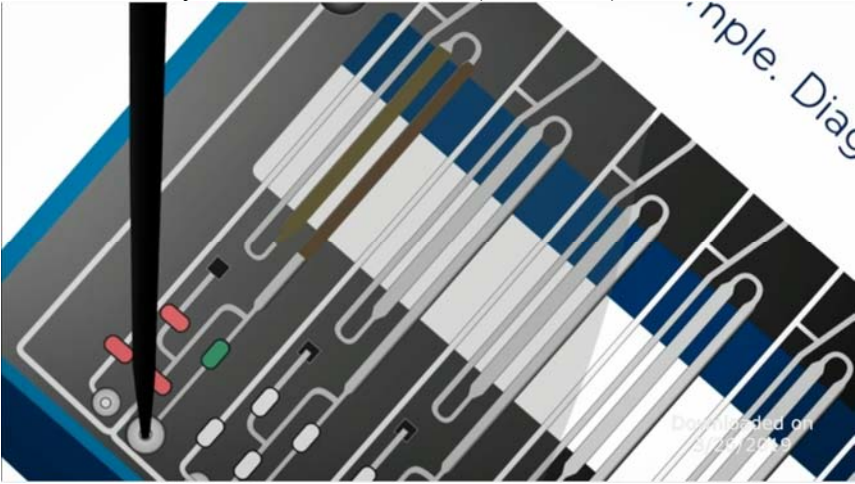
Claim	Claim Language	Infringement Evidence
		<p><i>NeuMoDx™ Molecular Systems</i>, NeuMoDx, http://www.neumodx.com/, last visited April 9, 2020 (Exhibit 48)</p> <ul style="list-style-type: none">“NeuMoDx™ Molecular Systems provide the industry’s first true continuous random-access solution and is scalable to meet the needs of the modern clinical laboratory. The ability to load samples and testing consumables on the fly offers up to 8 hours of operator walkaway capability. Room temperature stable reagents and consumables dramatically reduce waste resulting in unmatched flexibility. Liquid handling and transport is achieved through proven robotic technologies. Our proprietary and unitized microfluidic cartridge features autonomous lanes allowing for simultaneous processing of sample types and varying assays.” <p><i>NeuMoDx_Quant_HCV_CVS_2018.pdf</i> (Exhibit 18)</p> <ul style="list-style-type: none">Describing “...microfluidic cartridges capable of performing independent sample processing and real-time PCR.” <div data-bbox="782 675 1545 1144">A photograph of a NeuMoDx cartridge. The cartridge is blue with a silver microfluidic chip in the center. The chip has 12 sample ports along the bottom edge. The top of the cartridge has a white label with the text "Powerful. Simple. Diagnostics." and the NeuMoDx logo. Below the chip, there is a label with "CARTRIDGE" and a QR code. The bottom of the cartridge has a label with "LOT: 163272", "REF: 9000094", and "2018-12-31".</div> <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none">“NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System... The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.”

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		<p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMoDx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none">• “The NeuMoDx Molecular N96 and N288 are fully automated sample to result molecular diagnostics platforms. They provide continuous random access processing with initial results in one hour and operator walk away time of up to eight hours. NeuMoDx Molecular solutions utilize four distinct processes to produce the final patient results.” <i>Id.</i> at 0:00-0:28• “Liquid Handling Processing A: Lysis and Capture. Dispensing lysis buffer. Dispensing lysis buffer and patient specimen into extraction plate. The liquid handling robot delivers lysis buffer and patient specimen to the extraction plate, which has 24 independent wells which contain NeuDry affinity-coated paramagnetic beads. Each mixture is aspirated and dispensed five times to ensure homogeneity of the solution. During the transfer of patient specimen to the extraction plate the liquid handling robot uses pre-defined no-fly zones to reduce the potential of contamination.” <i>Id.</i> at 0:28-0:40• “Each extraction plate well is then heated independently for 10 minutes to ensure proper lysing and binding of the nucleic acids to the paramagnetic beads. The temperatures applied range from 37 degrees Celsius to 60 degrees Celsius, resulting in the flexibility to process a wide variety of DNA and RNA IVD and LDT tests simultaneously.” <i>Id.</i> at 1:05-1:16• “Liquid Handling Processing B: Extraction. After thoroughly mixing the solution in each well of the extraction plate, the crude lysate is independently aspirated from each well and transferred to the NeuMoDx cartridge.” <i>Id.</i> at 1:35-1:51• “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59

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		<div></div> <ul style="list-style-type: none">• “Liquid Handling Processing C: The Test Strip. After piercing the test strip, the liquid handling robot moves to the PCR port or p-port of the microfluidic cartridge, where it aspirates the eluate out of the cartridge into the pipette tip. Once the aspiration step is complete, the eluate is delivered to the appropriate wells in the NeuMoDx test strip, where it is dispensed and aspirated ten times to ensure homogeneous resuspension of the NeuDry PCR reagents. The sample mixes with primers and probes.” <i>Id.</i> at 3:12-3:36
1(b)	retaining polynucleotides from a sample on a plurality of binding particles in a process chamber under a first set of conditions,	<p>The accused workflow comprises retaining polynucleotides from a sample on a plurality of binding particles in a process chamber under a first set of conditions.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none">• “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none">• <i>Id.</i> at 0:40 (showing the extraction plate).

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		<div><ul style="list-style-type: none">• “Each extraction plate well is then autonomously heated for as little as six minutes to ensure proper lysing and binding of the nucleic acids to the paramagnetic beads. The temperatures applied range from 37° C to over 90° C, resulting in the flexibility to process a wide variety of DNA and RNA IVD and LDT tests simultaneously.” 1:07-1:32• <i>Id.</i> at 1:16 (showing binding of nucleic acids to paramagnetic beads).<div></div><ul style="list-style-type: none">• “Liquid Handling Processing B: Extraction. After thoroughly mixing the solution in each well of the extraction plate, the crude lysate is independently aspirated from each well and transferred to the NeuMoDx cartridge.” <i>Id.</i> at 1:35-1:51• “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:51-56</div>

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		<ul style="list-style-type: none">• 1:56 Microfluidic cartridge  <ul style="list-style-type: none">• “The liquid handling robot employs total aspiration and dispense monitoring pressure sensing to ensure each tip is securely seated into one of the 12 independent sample ports or s-ports of the cartridge. Once the pipette tip is secured, the entire volume of solution will be dispensed.” <i>Id.</i> at 2:02-2:07• 2:07 Dispensing into the s-ports

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		<div><p>Downloaded on 3/26/2019</p></div> <ul style="list-style-type: none">• “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” <i>Id.</i> at 2:24-28• 2:28 Lysate in the S-channel (extraction) <div><p>Sample. Diagram</p><p>Downloaded on 3/26/2019</p></div>

Claim	Claim Language	Infringement Evidence
		<p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none">• The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound nucleic acid is eluted using the NeuMoDx™ RELEASE Solution. <p>40500098_D-IFU-NeuMoDx-Extraction-Plate-US-ONLY (Exhibit 59)</p> <ul style="list-style-type: none">• “The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate lysis buffer in the NeuMoDx Extraction Plate and is subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres.” <i>Id.</i> at 1.• “The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution.” <i>Id.</i> at 1. <p>40600100_-Rev-D-IFU-NeuMoDx-WASH-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 58)</p> <ul style="list-style-type: none">• The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres.• The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 20)</p> <ul style="list-style-type: none">• The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the

Claim	Claim Language	Infringement Evidence
		<p>appropriate NeuMoDx lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres.</p> <ul style="list-style-type: none"> • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600103_Rev-D-IFU-NeuMoDx-Lysis-Buffer-4-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 66)</p> <ul style="list-style-type: none"> • The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of enriched Lim Broth is mixed with NeuMoDx Lysis Buffer 4 and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres dried in the NeuMoDx Extraction Plate. • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600104_Rev-D-IFU-NeuMoDx-Lysis-Buffer-3-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 65)</p> <ul style="list-style-type: none"> • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600106_Rev-D-IFU-NeuMoDx-Lysis-Buffer-1-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 63) NeuMoDx_Novel_Dry_Reagent_2017.pdf (Exhibit 80)</p> <ul style="list-style-type: none"> • “Three types of molecular diagnostic reagents were dried using unique formulations of select excipients: 1) Extraction reagents including magnetic particles with a nucleic acid affinity matrix, lytic enzymes, and encapsulated DNA/process controls.”

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		<div><div><p>ACCELERATED STABILITY OF NMDX EXTRACTION PLATES</p><table><tr><th></th><th>0wk</th><th>8.4wk</th><th>16.8wk</th><th>25.2wk</th><th>33.6wk</th><th>42.0wk</th><th>50.4wk</th></tr><tr><td>HCV</td><td>29.92</td><td>29.92</td><td>29.92</td><td>30.8</td><td>30.87</td><td>31.26</td><td>30.42</td></tr><tr><td>SPC2</td><td>29.23</td><td>29.23</td><td>29.23</td><td>29.63</td><td>29.47</td><td>29.91</td><td>29.38</td></tr><tr><td>G6S</td><td>28.84</td><td>28.84</td><td>28.84</td><td>28.3</td><td>28.44</td><td>28.84</td><td>28.81</td></tr><tr><td>SPC1</td><td>29.92</td><td>29.92</td><td>29.92</td><td>29.94</td><td>29.94</td><td>29.94</td><td>29.94</td></tr></table></div><div><p>CoS DNA Extractions with Dried Extractions Plate Stored for 52 wks at 40°C</p><p>HCV RNA Extractions with Dried Extractions Plate Stored for 52 wks at 40°C</p><table><tr><th>Days at 40°C</th><th>0</th><th>6</th><th>20</th><th>34</th><th>48</th><th>64</th><th>77</th><th>91</th><th>Avg</th><th>St</th><th>%CV</th></tr><tr><td>HCV</td><td>29.92</td><td>29.27</td><td>29.67</td><td>30.8</td><td>30.87</td><td>31.26</td><td>30.42</td><td>29.38</td><td>30.68</td><td>0.88</td><td>2.8</td></tr><tr><td>SPC2</td><td>29.23</td><td>29.23</td><td>29.23</td><td>29.63</td><td>29.47</td><td>29.91</td><td>29.38</td><td>29.38</td><td>29.61</td><td>0.3</td><td>1</td></tr><tr><td>G6S</td><td>28.84</td><td>28.84</td><td>28.84</td><td>28.3</td><td>28.44</td><td>28.84</td><td>28.84</td><td>28.84</td><td>28.84</td><td>0.33</td><td>1.3</td></tr><tr><td>SPC1</td><td>29.92</td><td>29.92</td><td>29.92</td><td>29.94</td><td>29.94</td><td>29.94</td><td>29.94</td><td>29.94</td><td>29.94</td><td>0.21</td><td>0.7</td></tr><tr><td>eq at 22°C (hrs)</td><td>0</td><td>3.4</td><td>11.4</td><td>14.6</td><td>21.4</td><td>27.4</td><td>44</td><td>62</td><td></td><td></td><td></td></tr></table></div><p>NMDx extraction plate is designed to be used on the NeuMoDx Molecular System to lyse bacteria and virus pathogens and capture DNA/RNA. It contains proteinase K, magnetic particles and DNA/RNA sample process control (SPC). The reagents were dried in a 24 well plate using the NMDx standard procedure, vacuum sealed foil pouch and stored at 40°C for accelerated study. The efficiency of the dried reagents was evaluated with two assays, Group B strep in Lim Broth and HCV in BaseMatrix. After equivalent to 1 yr at 22°C, no loss in activities was observed based on Ct and EPR values.</p></div>		0wk	8.4wk	16.8wk	25.2wk	33.6wk	42.0wk	50.4wk	HCV	29.92	29.92	29.92	30.8	30.87	31.26	30.42	SPC2	29.23	29.23	29.23	29.63	29.47	29.91	29.38	G6S	28.84	28.84	28.84	28.3	28.44	28.84	28.81	SPC1	29.92	29.92	29.92	29.94	29.94	29.94	29.94	Days at 40°C	0	6	20	34	48	64	77	91	Avg	St	%CV	HCV	29.92	29.27	29.67	30.8	30.87	31.26	30.42	29.38	30.68	0.88	2.8	SPC2	29.23	29.23	29.23	29.63	29.47	29.91	29.38	29.38	29.61	0.3	1	G6S	28.84	28.84	28.84	28.3	28.44	28.84	28.84	28.84	28.84	0.33	1.3	SPC1	29.92	29.92	29.92	29.94	29.94	29.94	29.94	29.94	29.94	0.21	0.7	eq at 22°C (hrs)	0	3.4	11.4	14.6	21.4	27.4	44	62			
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40600175_REV-C-SDS-NeuMoDx-Lysis-Buffer-1-Final.pdf (Exhibit 68)

Claim	Claim Language	Infringement Evidence																																				
		<div><div><div><div>Mixtures</div><div>Chemical Characterization: Mixture of a chemical and/or biological substances for <i>in vitro</i> diagnostic use.</div></div></div><div><table><tr><th colspan="4">Composition (Hazardous Components Only)</th></tr><tr><th>Name</th><th>Identifiers</th><th>%</th><th>GHS-US classification</th></tr><tr><td>Guanidine hydrochloride</td><td>CAS Number: 50-01-1</td><td>< 50%</td><td>Skin Irritation. 2; Eye Irritation. 2A</td></tr><tr><td>Maleic acid</td><td>CAS Number: 110-16-7</td><td><1%</td><td>Not a hazardous substance or mixture at this concentration.</td></tr><tr><td>Sodium azide</td><td>CAS Number: 26628-22-8</td><td>< 0.1%</td><td>Not a hazardous substance or mixture at this concentration.</td></tr></table></div><div><div>9.1</div><div>General Information</div><div><div>Form:</div><div>Liquid</div><div>Color:</div><div>Clear, with a slightly yellow tinge</div><div>Odor:</div><div>odorless</div><div>Odor Threshold:</div><div>Not determined</div><div>pH Value at 20°C (68°F):</div><div>4.45 – 4.9</div></div></div><div>40600176_Rev-C-SDS_-NeuMoDx-Lysis-Buffer-2-Final.pdf (Exhibit 69)</div><div><table><tr><th colspan="4">Composition (Hazardous Components Only)</th></tr><tr><th>Name</th><th>Identifiers</th><th>%</th><th>GHS-US classification</th></tr><tr><td>Guanidine hydrochloride</td><td>CAS Number: 50-01-1</td><td>< 50%</td><td>Skin Irritation. 2; Eye Irritation. 2A</td></tr><tr><td>Sodium azide</td><td>CAS Number: 26628-22-8</td><td>< 0.1%</td><td>Not a hazardous substance or mixture at this concentration.</td></tr></table></div></div>	Composition (Hazardous Components Only)				Name	Identifiers	%	GHS-US classification	Guanidine hydrochloride	CAS Number: 50-01-1	< 50%	Skin Irritation. 2; Eye Irritation. 2A	Maleic acid	CAS Number: 110-16-7	<1%	Not a hazardous substance or mixture at this concentration.	Sodium azide	CAS Number: 26628-22-8	< 0.1%	Not a hazardous substance or mixture at this concentration.	Composition (Hazardous Components Only)				Name	Identifiers	%	GHS-US classification	Guanidine hydrochloride	CAS Number: 50-01-1	< 50%	Skin Irritation. 2; Eye Irritation. 2A	Sodium azide	CAS Number: 26628-22-8	< 0.1%	Not a hazardous substance or mixture at this concentration.
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		<div><div>9.1 General Information</div><div><div>Form:</div><div>Color:</div><div>Odor:</div><div>Odor Threshold:</div><div>pH Value at 20°C (68°F):</div><div>Melting point/melting range:</div></div><div>Liquid</div><div>Clear, with a slightly yellow tinge</div><div>odorless</div><div>Not determined</div><div>4.2 – 5.2</div><div>Not determined</div></div> <div>40600177 Rev-C-SDS-NeuMoDx-Lysis-Buffer-3-Final.pdf (Exhibit 70)</div> <table><tr><th colspan="4">Composition (Hazardous Components Only)</th></tr><tr><th>Name</th><th>Identifiers</th><th>%</th><th>GHS-US classification</th></tr><tr><td>Guanidine hydrochloride</td><td>CAS Number: 50-01-1</td><td>< 50%</td><td>Skin Irritation. 2; Eye Irritation. 2A</td></tr><tr><td>Sodium azide</td><td>CAS Number: 26628-22-8</td><td>< 0.1%</td><td>Not a hazardous substance or mixture at this concentration.</td></tr></table> <div><div>9.1 General Information</div><div><div>Form:</div><div>Color:</div><div>Odor:</div><div>Odor Threshold:</div><div>pH Value at 20°C (68°F):</div><div>Melting point/melting range:</div></div><div>Liquid</div><div>Clear, with a slightly yellow tinge</div><div>Odorless</div><div>Not determined</div><div>4.9 – 5.1</div><div>Not determined</div></div> <div>40600112_Rev-B-SDS-NeuMoDx-Lysis-Buffer-4-FINAL.pdf (Exhibit 71)</div> <table><tr><th colspan="4">Composition (Hazardous Components Only)</th></tr><tr><th>Chemical Name</th><th>Identifiers</th><th>%</th><th>GHS-US classification</th></tr><tr><td>Triton X-100</td><td>CAS 9002-93-1</td><td>0.5-2.0%</td><td>Eye Irritation. 2 Harmful to Aquatic Life 3</td></tr><tr><td>Sodium Azide</td><td>CAS: 26628-22-8</td><td>< 0.1%</td><td>Not a hazardous substance or mixture at this concentration.</td></tr></table>	Composition (Hazardous Components Only)				Name	Identifiers	%	GHS-US classification	Guanidine hydrochloride	CAS Number: 50-01-1	< 50%	Skin Irritation. 2; Eye Irritation. 2A	Sodium azide	CAS Number: 26628-22-8	< 0.1%	Not a hazardous substance or mixture at this concentration.	Composition (Hazardous Components Only)				Chemical Name	Identifiers	%	GHS-US classification	Triton X-100	CAS 9002-93-1	0.5-2.0%	Eye Irritation. 2 Harmful to Aquatic Life 3	Sodium Azide	CAS: 26628-22-8	< 0.1%	Not a hazardous substance or mixture at this concentration.
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		<div><div>9.1General Information</div><div><div>Form:</div><div>Color:</div><div>Odor:</div><div>Odor Threshold:</div><div>pH Value at 20°C (68°F):</div><div>Liquid</div><div>Clear, with a slightly yellow tinge</div><div>odorless</div><div>Not determined</div><div>4.45 – 4.9</div></div></div> <div><p>“Patents”, http://www.neumodx.com/patents/, (Exhibit 47) demonstrating that NeuMoDx marks its products with US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; 9,452,430; 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; 10,010,888; 9,382,532; 9,540,636; 9,499,896; 10,239,060; 9,539,576; 10,226,771, 9,637,775; and 10,093,963</p><h2>PATENTS</h2><table><tr><th>Product</th><th>Patents</th></tr><tr><td>CARTRIDGE</td><td>US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.</td></tr><tr><td>P02 (overall system and method)</td><td>US Patent Nos. 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; and 10,010,888. CN Patent No. 201380009286.3.</td></tr><tr><td>EXTRACTION PLATE</td><td>US Patent Nos. 9,382,532; and 9,540,636. DE Patent No. 60 2013 056 932.0. DK Patent No. 2912174. EP Patent No. EP-B-2912174. ES Patent No. 300330453. FR Patent No. 2912174. GB Patent No. 2912174. IT Patent No. 502019000064944. NO Patent No. 2912174. SE Patent No. 2912174.</td></tr><tr><td>XPCR MODULE</td><td>US Patent Nos. 9,499,896; 10,239,060; 9,539,576; 10,226,771; 9,637,775; 10,093,963; 9,604,213; and 10,010,888.</td></tr></table><p>US9452430 (Exhibit 56)</p><ul style="list-style-type: none">Claim 9. The cartridge of claim 1, wherein the sealed waste chamber further defines a second external void parallel to the external void and configured to receive a magnet, wherein the second external void provides access to a magnetic capture segment of the fluidic pathway, wherein the magnetic capture segment is downstream of the sample</div>	Product	Patents	CARTRIDGE	US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.	P02 (overall system and method)	US Patent Nos. 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; and 10,010,888. CN Patent No. 201380009286.3.	EXTRACTION PLATE	US Patent Nos. 9,382,532; and 9,540,636. DE Patent No. 60 2013 056 932.0. DK Patent No. 2912174. EP Patent No. EP-B-2912174. ES Patent No. 300330453. FR Patent No. 2912174. GB Patent No. 2912174. IT Patent No. 502019000064944. NO Patent No. 2912174. SE Patent No. 2912174.	XPCR MODULE	US Patent Nos. 9,499,896; 10,239,060; 9,539,576; 10,226,771; 9,637,775; 10,093,963; 9,604,213; and 10,010,888.
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Claim	Claim Language	Infringement Evidence
		<p>port and upstream of the waste port.</p> <ul style="list-style-type: none">• Claim 10. The cartridge of claim 9, wherein the intermediate substrate includes a magnet proximal the second external void and the magnetic capture segment.• Claim 13. The cartridge of claim 12, wherein the first fluidic pathway comprises a capture segment, wherein the capture segment is s-shaped and progressively narrowing in an upstream-to-downstream direction• U.S. Patent No. 9,452,430 at col. 12:55-58 (“The magnet housing region 150 of the microfluidic cartridge 100 functions to provide access to and/or house at least one magnet 152 providing a magnetic field 156 for purification and isolation of nucleic acids.”)• U.S. Patent No. 9,452,430 at col. 16:31-43 (“The occlusion positions of the set of occlusion positions 141 of the first embodiment are preferably located such that occluding subsets of the set of occlusion positions 141 defines unique truncated fluidic pathways to controllably direct fluid flow. For example, as shown in FIG. 1D, occluding the fluidic pathway 165 at the first, third, fourth, and sixth occlusion positions 142, 144, 145, 147 forms a truncated pathway y which a volume of a sample fluid, comprising nucleic acids bound to magnetic beads and delivered into the sample port 114, may flow past the second occlusion position 143 into the capture segment 166 for isolation and purification of nucleic acids using the heating region 195 and the magnetic field 156. Nucleic acids bound to magnetic beads may thus be trapped within the capture segment 166 by the magnetic field 156, while other substances in the volume of sample fluid may pass into the waste chamber 130 by passing the fifth occlusion position 146.”)• U.S. Patent No. 9,452,430 at col. 17:9-31 (“Thereafter, as shown in FIG. 1G, the occlusion at the fourth occlusion position 145 may be reversed, creating a fifth truncated pathway, and release solution within the fluidic pathway 165 may be metered by pumping air through the fluid port 118, which functions to push a portion of the release solution into the waste chamber 130. A volume of release solution will still be maintained within the capture segment 166 at this stage. As shown in FIG. 1H, the first and the fourth occlusion positions 142, 145 may then be occluded to form a sixth truncated pathway sealing the volume of release solution, with the captured magnetic beads bound to nucleic acids, within the capture segment 166. The volume of the remaining release solution is therefore substantially defined by the microchannel volume between junctions in the fluidic pathway 165 near the fourth and sixth occlusion positions 145, 147, and may be any small volume but in a specific variation is precisely metered to be 23+/- 1 microliters. Release solution may be sealed within capture segments of other fluidic pathways using a similar process. A heater may then be provided at the sixth truncated pathway, inducing a pH shift within the sixth truncated pathway to unbind nucleic acids from the magnetic beads.”) <p>US9050594 (Exhibit 24)</p>

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module. • Claim 24. The system of claim 23, further comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample, a lysing reagent, and a sample process control, wherein the capture plate facilitates production of at least one biological sample combined with magnetic beads; an assay strip comprising at least one reagent well containing molecular diagnostic reagent volume configured to be combined with a nucleic acid volume of the set of nucleic acid volumes to produce at least one nucleic acid-reagent mixture; and a liquid handling system configured to transfer at least one biological sample combined with magnetic beads from the capture plate to the molecular diagnostic module, transfer at least one nucleic acid-reagent mixture from the assay strip back to the molecular diagnostic module. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic

Claim	Claim Language	Infringement Evidence
		<p>acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at col. 2:49-58 (“As shown in FIGS. 1A-1B and 7A, an embodiment of a system 100 for processing and detecting nucleic acids comprises: a capture plate 110 configured to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119; a molecular diagnostic module 130 comprising a microfluidic cartridge receiving the module 140, heating and cooling subsystems 150, a magnet 160, a valve actuation sub-system 170, an optical subsystem 180; and an assay strip configured to facilitate mixing of molecular diagnostic reagents with a nucleic acid volume.”) • U.S. Patent No. 9,050,594 at col. 3:14-28 (“In one example workflow of the system 100, a liquid handling system 250 aspirates a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), and dispenses the set of biological samples into a capture plate 110 to be lysed and combined with magnetic beads (containing a proprietary affinity coating to bind the nucleic acids to the magnetic beads) by a capture plate module 120. The liquid handling system 250 then aspirates substantially all of each sample of the set of lysed biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate no, and dispenses the set of magnetic bead-samples into a microfluidic cartridge 210, aligned within a cartridge receiving module 140 of a molecular diagnostic module 130, and configured to be manipulated by the molecular diagnostic module 130.”) • U.S. Patent No. 9,050,594 col. 4:15-25 (“The set of wells 112 of the capture plate substrate 111 function to receive at least one biological sample which con-tain or are suspected of potentially containing nucleic acids, and to facilitate combination of the biological sample with a set of magnetic beads 119. Preferably, the wells 113 are each configured to accommodate not only a biological sample, but also to facilitate mixing of the biological sample with a set of magnetic beads 119 (e.g., using a pipettor, the liquid handling system 250 or other apparatus), which preferably are pre-loaded in wells 112, or alternatively may be added by an operator”) • U.S. Patent No. 9,050,594 at col. 23:32-41 (“As described in Section 1, an embodiment of the liquid han-dling system 250 is configured to aspirate a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), dispense the set of biological samples into a capture 35 plate no to be lysed and combined with magnetic beads by a capture plate module 120, aspirate the set of biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate 110, and dispense the set of magnetic bead-samples into microfluidic

Claim	Claim Language	Infringement Evidence
		<p>cartridge 210 located in a molecular diagnostic module 130.”)</p> <ul style="list-style-type: none"> U.S. Patent no. 9,050,594 at col 28:53-58 (“Step S430 recites transferring each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways, and functions to isolate each of the set of nucleic acid-magnetic bead samples within separate pathways for further processing.”) <p>US9339812 (Exhibit 26)</p> <ul style="list-style-type: none"> Claim 2: The method of claim 1, further comprising combining the biological sample with a quantity of magnetic beads, to produce a magnetic bead-sample mixture, prior to dispensing the biological sample into the fluidic pathway through the sample port. Claim 15. A method for processing and detecting nucleic acids from a set of biological samples with a cartridge having a set of fluidic pathways defined by an elastomeric layer, the method comprising: combining each biological sample of the set of biological samples with a quantity of magnetic beads to produce a set of nucleic acid-magnetic bead samples; aligning the cartridge at a cartridge platform of a molecular diagnostic module, the cartridge platform having a set of slots, and the molecular diagnostic module having a cam module contacting a set of pins aligned with the set of slots; transferring substantially all of each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways; moving the cam module by transitioning the actuator into an extended configuration, thereby displacing a subset of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the elastomeric layer to occlude at least one fluidic pathway of the set of fluidic pathways at a subset of occlusion positions for controlling a flow through the fluidic pathway; and detecting nucleic acids using a set of detection chambers coupled to the set of fluidic pathways. Claim 18. The method of claim 15, wherein combining each biological sample of the set of biological samples with a quantity of magnetic beads comprises combining each biological sample of the set of biological samples with a quantity of magnetic beads treated to be at least one of positively charged, magnetic, paramagnetic, and supraparamgetic [sic].” Claim 29. A method for processing and detecting nucleic acids within a cartridge having a fluidic pathway including a set of occlusion positions defined by an elastomeric layer of the cartridge, the method comprising: aligning the cartridge at a cartridge platform of a molecular diagnostic module, the cartridge platform having a set of slots, and the molecular diagnostic module having a cam module contacting a set of pins aligned with the set of slots and an actuator that provides relative displacement between the cartridge platform and the set of pins; moving the cam module by transitioning the actuator into an extended configuration, thereby displacing a first sub-set of the set of pins through he set of slots of the cartridge platform, and thereby manipulating the elastomeric layer to occlude the fluidic pathway at a

Claim	Claim Language	Infringement Evidence
		<p>first subset of the set of occlusion positions, thus defining a first truncated fluidic pathway passing through a magnetic field for controlling a flow through the fluidic pathway; capturing a sample of nucleic acids bound to magnetic beads within the first truncated fluidic pathway, by the magnetic field; and moving the cam module, thereby displacing a second subset of the set of pins through the set of slots of the cartridge platform and thereby manipulating the elastomeric layer to occlude the fluidic pathway, through the elastomeric layer, at a second subset of the set of occlusion positions, thus defining a second truncated fluidic pathway containing the sample of nucleic acids bound to magnetic beads.</p> <ul style="list-style-type: none"> • U.S Patent No. 9,339,812 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) • U.S. Patent No. 9,339,812 at col. 3:14-20 (“In one example workflow of the system 100, a liquid handling system 250 aspirates a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), and dispenses the set of biological samples into a capture plate 110 to be lysed and combined with magnetic beads (containing a proprietary affinity coating to bind the nucleic acids to the magnetic beads) by a capture plate module 120.”) • U.S. Patent No. 9,339,812 at col. 4:15-25 (“The set of wells 112 of the capture plate substrate 111 function to receive at least one biological sample which contain or are suspected of potentially containing nucleic acids, and to facilitate combination of the biological sample with a set of magnetic beads 119. Preferably, the wells 113 are each configured to accommodate not only a biological sample, but also to facilitate mixing of the biological sample with a set of magnetic beads 119 (e.g., using a pipettor, the liquid handling system 250 or other apparatus), which preferably are pre-loaded in wells 112, or alternatively may be added by an operator.”) <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> • Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a

Claim	Claim Language	Infringement Evidence
		<p>biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none">• Claim 4. The method of claim 3, wherein incubating the moiety-sample mixture comprises heating the moiety-sample solution to a temperature in the range of 25-95° C. for 5-60 minutes, thus simultaneously lysing the biological sample and facilitating binding of nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles.• Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the microfluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20 uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction.• Claim 18. The method of claim 17, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety-sample mixture from the process chamber; occluding

Claim	Claim Language	Infringement Evidence
		<p>the fluidic pathway of the cartridge at a set of occlusion positions upon displacement of the first subset of the set of pins to generate a path through a magnetic field, and to a waste chamber of the cartridge; and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber.</p> <ul style="list-style-type: none"> • Claim 19. A method for nucleic acid isolation from a biological sample, comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution includes a set of affinity moiety-coated microparticles, comprising a set of microparticles amide-bonded to at least one of poly(allylamine) of molecular weight <30,000 Da and Polypropylenimine tetramine dendrimer Generation 1; producing a moiety-sample mixture upon combination of the binding moiety solution with the biological sample; producing a set of moiety-bound nucleic acid particles upon incubation of the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of the set of pins includes reversing displacement of at least one pin of the first subset of the set of pins, and reversing occlusion of a portion of the fluidic pathway. • U.S. Patent No. 9,382,532 at col.3:35-43 (“The method 100 can be performed in any container or process chamber that is configured to contain a suitable concentration of affinity moiety-coated microparticles, facilitate suitable buffer conditions to allow for binding (e.g., buffer conditions providing a suitably low pH), contain suitable amounts of proteolytic or other enzymes for effective lysis or removal of inhibitory substances, and provide suitable thermal conditions that collectively enable binding of nucleic acids to the affinity moiety-coated microparticles.”) • U.S. Patent No. 9,382,532 at 4:35-55 (“In a specific example of this variation of Step S110, the microparticles are magnetic beads (e.g., magnetic, paramagnetic, superparamagnetic) with any suitable hydrophilicity (e.g., hydrophobic, hydrophilic), wherein the magnetic beads are coated with the affinity moiety and simultaneously received within the process chamber along with a low-pH buffer solution, proteolytic enzymes, and lytic reagents. In this specific example, magnetic separation can be used to facilitate further processing and isolation of nucleic acids bound to the affinity moieties coupled to magnetic beads. In another specific example of this variation, the microparticles are beads

Claim	Claim Language	Infringement Evidence
		<p>of a suitable size coated with the affinity moiety, and are simultaneously received within the process chamber along with a suitable buffer solution, proteolytic enzymes, and lytic reagents. In this specific example, sized-based separation can be used to facilitate further processing and isolation of nucleic acids bound to the affinity moieties coupled to the suitably-sized beads. The binding moiety solution of Step S110 can additionally or alternatively comprise any suitable affinity moiety or combination of affinity moiety delivered by any suitable mechanism or substrate.”)</p> <ul style="list-style-type: none">• U.S. Patent No. 9,382,532 at 4:56-5:2 (“Step S120 recites mixing the binding moiety solution with a biological sample, within the process chamber, in order to produce a moiety-sample solution, which functions to initiate lysis of the biological sample and enable target nucleic acids to bind to affinity moieties of the binding moiety solution. Preferably, binding of target nucleic acids to affinity moieties is facilitated by the appropriate pH of the binding solution, as shown in FIG. 1C; however, binding can be facilitated by any other suitable mechanism. In a variation involving an appropriate pH in the binding solution, mixing and binding can occur at a low pH, which produces a positively charged affinity moiety that is attracted to negatively charged nucleic acid molecules. Specific examples of affinity moieties that function via a pH shift are described in Section 2 below.”)• U.S. Patent No. 9,382,532 at 5:3-7 (“In Step S120, the process chamber can be any suitable vessel, as shown in FIG. 1A, or a suitable capture plate, such as that described in U.S. patent application Ser. No. 13/766,359, entitled “System and Method for Processing and Detecting Nucleic Acids”, as shown in FIG. 1B.”)• U.S. Patent No. 9,382,532 at 5:42-6:2 (“ Step S130 recites incubating the moiety-sample solution during a time window, and functions to produce a lysed moiety-sample solution comprising a moiety-bound nucleic acid volume (e.g., a volume of nucleic acids reversibly bonded to the set of affinity moiety-coated microparticles) and a waste volume. In Step S130, the moiety-sample solution can be incubated using any suitable heating apparatus, as shown in FIG. 1A, or a suitable capture plate heater, such as that described in U.S. patent application Ser. No. 13/766,359, entitled "System and Method for Processing and Detecting Nucleic Acids", as shown in FIG. 1B. In Step S130, the nucleic acid is released from within the cell or other structure that it is contained within, and binds to the microparticles coupled with the affinity moiety, while other unbound components form a waste volume for later removal, as shown in FIG. 1 C. Preferably, the process chamber containing the moiety-sample solution (e.g., lysis, clean-up, binding reagents and the biological sample) is incubated for a defined period of time at a temperature preferably in the range of 25-95 C, wherein time and temperature parameters are biological sample-dependent. Example parameters for different biological samples are described briefly below, and further in Section 3 below. Alternatively, the moiety-sample solution can be transferred to another vessel for incubation in variations of Step S130. Furthermore, in variations of Steps S110, S120, and S130, any or all of the lysis, proteolytic and binding steps can occur simultaneously in the process chamber or any other suitable vessel, and are not required to be discrete steps.”)

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> U.S. Patent No. 9,382,532 at 7:14-54 “In Step S140, the lysed moiety-sample solution can be processed within the process chamber to separate the moiety-bound nucleic acid volume from the waste volume; however, the lysed moiety-sample solution can alternatively be transferred to another suitable vessel for separation of the moiety-bound nucleic acid volume from the waste volume. In a first variation, a pipetting system (automatic or manual) can be used to remove the waste volume (e.g., supernatant liquid), and multiple aspirations by the pipetting system may be necessary to ensure as complete a removal of the supernatant as possible. In an example of the first variation, a 1000 micro liter pipette tip can be used to perform gross removal of the waste volume in a first aspiration followed by the use of a finer pipette tip (e.g., 100-200 microliter tip) in additional aspirations, to remove the remainder of the waste volume. In the example, the removal of the waste volume occurs close to the bottom of the process chamber to provide complete liquid removal with minimal bubbling. In a second variation, the lysed moiety-sample solution can be transferred to a vessel that enables the moiety-bound nucleic acid volume to be captured and the waste volume to be removed in a flow through manner, either against the pores of a filter or in the presence of a magnetic field. In the second variation, the microparticles with bound nucleic acids are retained in a filter zone or a magnetic field zone of the vessel, and the liquid portion is flowed into a "waste chamber". In a specific example of the second variation, a system (such as the one described in U.S. patent application Ser. No. 13/766,359, entitled "System and Method for Processing and Detecting Nucleic Acids") can be used to transfer the lysed moiety-sample solution into a fluidic pathway of a cartridge (such as the one described in U.S. patent application Ser. No. 13/765,996, entitled "Microfluidic Cartridge for Processing and Detecting Nucleic Acids"). In the specific example, the lysed moiety-sample solution can be retained by a magnetic field within a portion of the fluidic pathway upon occlusion of the fluidic pathway at a suitable set of occlusion positions, in order to separate the moiety-bound nucleic acid volume from the waste volume. The waste volume can then be removed by pushing the waste volume to a waste chamber of the cartridge.” U.S. Patent No. 9,382,532 at 24:1-14 “A first illustration of the eighteenth example, as shown in FIG. 22A, of a fluidic pathway 165 preferably comprises an initial segment 174 fluidically coupled to a fluid channel 119 coupled to a shared fluid port 118, a sample segment 175 coupled to a sample port 114 and to the initial segment 174, and an s-shaped capture segment 166, configured to pass through the heating region 195 and a magnetic field 156, coupled to the initial segment 174 and the sample segment 175. In an alternative illustration of the eighteenth example, 10 the s-shaped capture segment 166 may comprise an initial wide arc 166 to provide a greater surface area for magnetic bead capture. In another illustration of the eighteenth example, the capture segment 166 may alternatively be a progressively narrowing s-shaped capture segment 166.” U.S. Patent No. 9,382,532 at FIG. 22A:

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		<div data-bbox="801 266 1596 513"></div> <p>FIGURE 22A</p> <ul style="list-style-type: none">• U.S. Patent No. 9,382,532 at 25:30-50 (“A volume of release solution will still be maintained within the capture segment 166 at this stage. The first and the fourth occlusion positions 142, 145 may then be occluded to form a sixth truncated pathway sealing the volume of release solution, with the captured magnetic beads bound to nucleic acids, within the capture segment 166. The volume of the remaining release solution is therefore substantially defined by the microchannel volume between junctions in the fluidic pathway 165 near the fourth and sixth occlusion positions 145, 147, and maybe any small volume but in a specific variation is precisely metered to be 23+/-1 microliters. Release solution may be sealed within capture segments of other fluidic pathways using a similar process. A heater may then be provided at the sixth truncated pathway, inducing a pH shift within the sixth truncated pathway to unbind nucleic acids from the magnetic beads.”)• U.S. Patent No. 9,382,532 at 27:17-42 (“The occlusion positions of the set of occlusion positions 141' of the second illustration are preferably located such that occluding of subsets of the set of occlusion positions 141' defines unique truncated fluidic pathways to controllably direct fluid flow. For example, occluding the fluidic pathway 165' at the first, fourth, sixth, tenth, and eleventh occlusion positions 142', 145', 147', 158', 159' forms a truncated pathway by which a volume of a sample fluid, comprising nucleic acids bound to magnetic beads and delivered into the sample port 114, may flow into the capture segment 166' for isolation and purification of nucleic acids using the heating region 195 and the magnetic field 156. Nucleic acids bound to magnetic beads may thus be trapped within the capture segment 166' by the magnetic field 156, while other substances in the volume of sample fluid may pass into the waste chamber 130 by passing the fifth occlusion position 146'. Following this subset of occlusion positions, the occlusion at the first occlusion position 142' may be reversed, and the fluidic pathway 165' may be occluded at the second occlusion position 143' to form a second truncated pathway by which a wash fluid may be delivered through the fluid port 118, into the capture segment 166' (thus washing the trapped magnetic beads), and into the waste chamber 130 by passing the fifth occlusion position 146'. A volume of air may then be pumped through the fluid port 118 to flush any remaining wash solution into the waste chamber 130.”)• U.S. Patent No. 9,050,594 at col. 28:34-38 (“Step S420 recites heating the set of magnetic bead-sample mixtures to

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		<p>produce a set of nucleic acid-magnetic bead samples, and functions to incubate the set of magnetic bead-sample mixtures in order to lyse biological matter, and release nucleic acids to be bound to magnetic beads.”)</p> <ul style="list-style-type: none"> U.S. Patent no. 9,050,594 at col 28:53-58 (“Step S430 recites transferring each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic path-ways, and functions to isolate each of the set of nucleic acid-magnetic bead samples within separate pathways for further processing.”) <p>US9441219 (Exhibit 53)</p> <ul style="list-style-type: none"> Claim 7: The molecular diagnostic module of claim 1, further comprising: a capture plate comprising a well containing a set of magnetic beads, a lysing reagent, and a sample process control, configured to be combined with the biological sample, wherein the capture plate facilitates production of a magnetic bead-sample from the biological sample and the set of magnetic beads; an assay strip comprising a reagent well containing a molecular diagnostic reagent volume configured to be combined with the nucleic acid volume processed from the magnetic-bead sample, thereby generating a nucleic acid-reagent mixture; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the cartridge, transfer the nucleic acid volume from the cartridge to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip back to the cartridge. Claim 14. The system of claim 8, further comprising a capture plate comprising a well containing a set of magnetic beads, a lysing reagent, and a sample process control, configured to be combined with the biological sample, wherein the capture plate facilitates production of a magnetic bead-sample from the biological sample and the set of magnetic beads; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the cartridge, and configured to transfer a nucleic acid volume processed from the magnetic bead-sample from the cartridge. U.S. Patent No. 9,441,219 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) U.S. Patent No. 9,441,219 at col. 3:28-35 (“The liquid handling system 250 then aspirates substantially all of each

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		<p>sample of the set of lysed biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate no, and dispenses the set of magnetic bead-samples into a microfluidic cartridge 210, aligned within a cartridge receiving module 140 of a molecular diagnostic module 130, and configured to be manipulated by the molecular diagnostic module 130.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,441,219 at col. 4:23-33 (“The set of wells 112 of the capture plate substrate 111 function to receive at least one biological sample which contain or are suspected of potentially containing nucleic acids, and to facilitate combination of the biological sample with a set of magnetic beads 119. Preferably, the wells 113 are each configured to accommodate not only a biological sample, but also to facilitate mixing of the biological sample with a set of magnetic beads 119 (e.g., using a pipettor, the liquid handling system 250 or other apparatus), which preferably are preloaded in wells 112, or alternatively may be added by an operator.”) • U.S. Patent No. 9,441,219 at col. 27:42-67 (“An embodiment of a method 400 for processing and detecting nucleic acids from a set of biological samples comprises: combining each biological sample of the set of biological samples with a quantity of magnetic beads to produce a set of magnetic bead-sample mixtures S410; heating the set of magnetic bead-sample mixtures to produce a set of nucleic acid-magnetic bead samples S420; transfer ring each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways S430; producing a set of nucleic acid volumes from the set of nucleic acid-magnetic bead samples S440; combining each nucleic acid volume of the set of nucleic acid volumes with a molecular diagnostic reagent of a set of molecular diagnostic reagents to produce a set of nucleic acid-reagent mixtures S450; transferring each of the set of nucleic acid-reagent mixtures, through the corresponding fluidic pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers S460; and receiving light from the set of nucleic acid-reagent mixtures S470. The method 400 may further comprise generating a set of data based on light received form the set of nucleic acid-reagent mixtures S480. The method 400 functions to isolate and extract a set of nucleic acid volumes from a biological sample, and to facilitate analysis of the nucleic acid volumes according to at least one molecular diagnostic protocol.”) • U.S. Patent No. 9,441,219 at col. 29:10-19 (“Step S420 recites heating the set of magnetic bead-sample mixtures to produce a set of nucleic acid-magnetic bead samples, and functions to incubate the set of magnetic bead-sample mixtures in order to lyse biological matter, and release nucleic acids to be bound to magnetic beads. Preferably, Step S420 comprises heating a capture plate containing the set of magnetic bead-sample mixtures for a specified amount of time at a specified temperature, and may additionally include cooling the set of magnetic bead-sample mixtures.”) • U.S. Patent No. 9,441,219 at col. 29:30-35 (“Step S430 recites transferring each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways, and functions to isolate each of the set of nucleic acid-magnetic bead samples within separate pathways for further

Claim	Claim Language	Infringement Evidence
		<p>processing.”)</p> <ul style="list-style-type: none">• U.S. Patent No. 9,441,219 at col. 30:13-29 (“Step S440 preferably includes providing a magnetic field S441. Such that each fluidic pathway in the set of fluidic pathways is configured to cross the magnetic field. Preferably, the set of nucleic acid magnetic bead samples is captured and isolated within portions of the set of fluidic pathways crossing the magnetic field. Step S440 may further comprise providing a heater configured to span a heating region of the set of fluidic pathways S442, but may alternatively comprise providing multiple heaters or altogether omit providing a heater. In embodiments wherein multiple heaters are provided, each heater is preferably independent to allow independent control of heating time and temperature for each sample. Step S442 functions to provide a heater, which, in combination with a release solution that provides a pH shift, facilitate a rapid and efficient unbinding of the nucleic acids from magnetic beads.”) <p>US9540636 (Exhibit 54)</p> <ul style="list-style-type: none">• Claim 1: A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; and washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway.”• Claim 5. The method of claim 4, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety sample mixture from the process chamber, occluding the fluidic pathway of the cartridge at a set of occlusion positions upon displacement of pins of the set of pins to generate a path through a magnetic field, and to a waste chamber, and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber.• Claim 6. The method of claim 3, wherein incubating the moiety-sample mixture comprises heating the moiety-sample solution to a temperature above 25° C for at least 5 minutes, thus simultaneously lysing the biological

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		<p>sample and facilitating binding of nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles.</p> <ul style="list-style-type: none"> • Claim 7. The method of claim 3, wherein washing the set of moiety-bound nucleic acid particles comprises aspirating the moiety-sample mixture; receiving the cartridge at the cartridge receiving module comprising the set of pins and a cam card interfacing with the set of pins; transitioning the cartridge to an active configuration that disposes the cartridge to a position that is proximal to the set of pins; displacing the first subset of the set of pins in the active configuration of the cartridge, upon translation of the cam card relative to the set of pins, thereby occluding the fluidic pathway of the cartridge at a set of occlusion positions; delivering the moiety-sample mixture into the fluidic pathway, wherein the fluidic pathway is configured to pass through a magnetic field and is coupled to a waste chamber, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field; and delivering a wash solution through the fluidic pathway and into the waste chamber in a continuous flow operation. • Claim 10. The method of claim 3, further comprising releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles, wherein releasing the nucleic acid sample comprises: occluding the fluidic pathway of the cartridge, comprising the process chamber, at a set of occlusion positions, upon displacement of pins of the set of pins, to define a path through a magnetic field; delivering the set of moiety-bound nucleic acid particles into the path of the fluidic pathway; and delivering an elution solution into the fluidic pathway, thereby inducing a pH shift configured to release the nucleic acid sample from the set of moiety-bound nucleic acid particles. • Claim 14. A method for nucleic acid extraction, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles; mixing the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and target RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; and magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the microfluidic pathway of the cartridge. • Claim 17: A method for nucleic acid isolation from a biological sample, comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution includes a set of affinity moiety-coated microparticles; producing a moiety-sample mixture upon combination of the binding moiety solution with the biological sample; producing a set of moiety-bound nucleic acid particles upon incubation of the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated

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		<p>microparticles; occluding a fluidic pathway of a cartridge upon displacement of a first subset of pin at the cartridge comprising the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles, within the fluidic pathway of the cartridge; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution.</p> <ul style="list-style-type: none">U.S. Patent No. 9,540,636 at Abstract (“A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, in order to produce a moiety-sample mixture; incubating the moiety-sample mixture during a time window, thereby producing a solution comprising a set of moiety-bound nucleic acid particles and a waste volume; separating the set of moiety-bound nucleic acid particles from the waste volume; washing the set of moiety-bound nucleic acid particles; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles. The method preferably utilizes a binding moiety comprising at last one of poly(allylamine) and polypropylenimine tetramine dendrimer, both of which reversibly bind and unbind to nucleic acids based upon environmental pH.”) <p>FIGURE 1C</p> <ul style="list-style-type: none">U.S. Patent No. 9,540,636 at col. 5:1-9 (“Step S120 recites mixing the binding moiety solution with a biological sample, within the process chamber, in order to produce a moiety-sample solution, which functions to initiate lysis of the biological sample and enable target nucleic acids to bind to affinity moieties of the binding moiety solution. Preferably, binding of target nucleic acids to affinity moieties is facilitated by the appropriate pH of the binding solution, as shown in FIG. 1C; however, binding can be facilitated by any other suitable mechanism.”)U.S. Patent No. 9,540,636 at col. 6:2-9 (“Preferably, the process chamber containing the moiety-sample solution (e.g., lysis, clean-up, binding reagents and the biological sample) is incubated for a defined period of time at a

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		<p>temperature preferably in the range of 25-95 C, wherein time and temperature parameters are biological sample-dependent. Example parameters for different biological samples are described briefly below, and further in Section 3 below.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,540,636 at col. 7:29-52 (“In Step S140, the lysed moiety-sample solution can be processed within the process chamber to separate the moiety-bound nucleic acid volume from the waste volume: however, the lysed moiety-sample solution can alternatively be transferred to another suitable vessel for separation of the moiety-bound nucleic acid volume from the waste volume. In a first variation, a pipetting system (automatic or manual) can be used to remove the waste volume (e.g., supernatant liquid), and multiple aspirations by the pipetting system may be necessary to ensure as complete a removal of the supernatant as possible. In an example of the first variation, a 1000 microliter pipette tip can be used to perform gross removal of the waste volume in a first aspiration followed by the use of a finer pipette tip (e.g., 100-200 microliter tip) in additional aspirations, to remove the remainder of the waste volume. In the example, the removal of the waste volume occurs close to the bottom of the process chamber to provide complete liquid removal with minimal bubbling. In a second variation, the lysed moiety-sample solution can be transferred to a vessel that enables the moiety-bound nucleic acid volume to be captured and the waste volume to be removed in a flow through manner, either against the pores of a filter or in the presence of a magnetic field.”) U.S. Patent No. 9,540,636 at col. 14:19-22 (“In an example of Step S130, RNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 60 C.”) U.S. Patent No. 9,540,636 at col. 14:48-56 (“In the second example, 500 uL of M4 transport media containing a nasal Swab (donor) was spiked with 2 L of either a 10 dilution (high) or a 10'(low) dilution of EV RNA (purified from 200 uL viral particle lysate and eluted in 20 u, total volume) and then mixed with 500 uL of RNA Collection Buffer 1 (CBR-1) and 0.4 mg of Proteinase K in examples of Steps S110 and S120. RNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 60 C. in an example of Step S130.”) U.S. Patent No. 9.540,636 at col. 15:22-30 (“In the third example, 500 uL of UTM transport media containing a nasal swab (donor) was spiked with 2 ul of a 10" dilution of EV RNA (purified from 200 uL viral particle lysate and eluted in 20 uL total volume) and then mixed with 500 uL of RNA Collection Buffer 1 (CBR-1) and 0.6 mg of Proteinase K in examples of Steps S110 and S120. RNA was allowed to bind to the PAA affinity particles coated onto magnetic microparticles for 10 minutes at 60 C. in an example of Step S130.”) U.S. Patent No. 9,540,636 at col. 25:52-60 (“A first illustration of the eighteenth example, as shown in FIG.22A, of a fluidic pathway 165 preferably comprises an initial segment 174 fluidically coupled to a fluid channel 119 coupled to a shared fluid port 118, a sample segment 175 coupled to a sample port 114 and to the initial segment 174, and an S-shaped capture segment 166, configured to pass through the heating region 195 and a magnetic field 156,

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		<p>coupled to the initial segment 174 and the sample segment 175.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 15:60-67 (“In the fourth example, 500 uL of M4 transport media containing a nasal Swab (donor) was spiked with 2 LL of ten-fold dilutions of EV viral particle lysate and then mixed with 500 uL of RNA Collection Buffer 1 (CBR-1) and 0.4 mg of Proteinase K in examples of Steps S110 and S120. RNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 60 C. in an example of Step S130.”) • U.S. Patent No. 9,540,636 at col. 16:48-58 (“In the fifth example, 500 u, of Urine or Plasma was spiked with 10pg of GBS DNA and then mixed with 500 uL of DNA Collection Buffer 2 (CBD-2) in examples of Steps S110 and S120. Alternately, a buccal swab was added to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg. Proteinase K and then spiked with 10 pg of GBS DNA in other examples of Steps S110 and S120. DNA was allowed to bind to the DABAM affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature or 60 C depending on matrix used in examples of Step S130.”) • U.S. Patent No. 9,540,636 at col. 18: 31-37 (“In the eighth example, a buccal Swab (obtained from a donor) was added to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg. Proteinase K and then spiked with 10 pg of GBS DNA in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37 C in an example of Step S130.”) • U.S. Patent No. 9,540,636 at col. 19:2-13 (“In the ninth example 500 uL of M4 Transport Media (M4) or Universal Transport Media (UTM) containing a buccal Swab (obtained from a donor) was spiked with 10 pg of GBS DNA and then mixed with 500 uL of DNA Collection Buffer 3 (CBD-3) and 0.4 mg of Proteinase K in examples of Steps S110 and S120. For comparison, “Dry Swab’ samples were prepared by adding a buccal swab to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg. Proteinase K and then spiked with 10 pg of GBS DNA. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37 C in an example of Step S130.”) • U.S. Patent No. 9,540,636 at col. 19:44-51 (“In the tenth example, 100 uL whole blood (donor, obtained from Bioreclamation, Inc.) was added to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg. Proteinase K and then spiked with 10 pg of GBS DNA in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37 C in an example of Step S130.”) • U.S. Patent No. 9,540,636 at col. 22:60-67 (“In the fifteenth example, 500 uL of Urine (obtained from a donor) was spiked with 10 pg of GBS DNA and then mixed with 500 uL of DNA Collection Buffer 2 (CBD-2) in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature, 37 C, 45 C, or 60 C in examples of Step S130.”) • U.S. Patent No. 9,540,636 at col. 24:16-22 (“In the seventeenth example, 500 uL of M4 was spiked with ten-fold serial

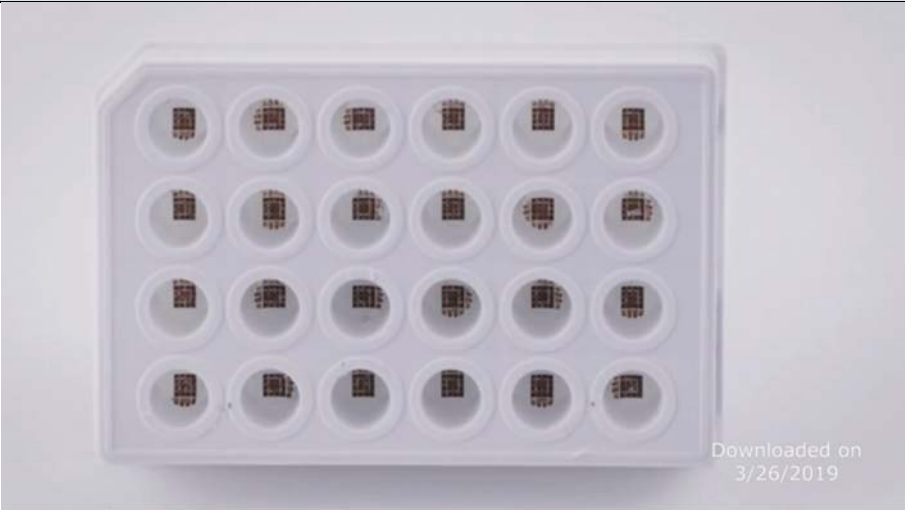

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		<p>dilutions of 1 uL of EV viral particle lysate and 1 LL of GBS DNA and then mixed with 500 uL of RNA Collection Buffer 3 (CBR-3) in examples of Steps S110 and S120. RNA and DNA were allowed to bind to the PAA affinity moieties for 10 minutes at 37C in an example of Step S130.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,540,636 at col. 27:4-17 (“Thereafter in the first illustration, as shown in FIG. 22C, the fluidic pathway 165 may be occluded at the second occlusion position 143 and the occlusion at the first occlusion 142 may be reversed, thus creating a third truncated pathway as shown in FIG. 22B. A release solution may then be delivered through the fluid port 118, into the capture segment 166, and to the waste chamber 130 by passing the fifth occlusion position 146. The release solution may then be sealed within a fourth truncated pathway (including the capture segment 166) of the fluidic pathway 165 by occluding the fluidic pathway at the fifth occlusion position 146. A release solution may then be delivered to other fluidic pathways of the set of fluidic pathways 160.”) <p>US9604213 (Exhibit 30)</p> <ul style="list-style-type: none"> Claim 1: A system for processing and detecting nucleic acids in cooperation with a cartridge comprising a heating region defined at a first surface, and a magnet housing region defined at a second surface in thermal communication with the first surface, the system comprising: a capture plate configured to facilitate combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate and separate nucleic acids from the set of magnetic beads, comprising: a cartridge platform configured to receive the cartridge and comprising a magnet receiving slot aligned with the second surface during operation, a heater configured to transmit heat to the heating region at the first surface during operation, and a magnet coupled to a magnet heating element that heats the magnet during operation with the magnet proximal the second surface, the magnet configured to pass through the magnet receiving slot into the magnet housing region during operation, thereby facilitating separation of a nucleic acid volume from the magnetic bead-sample and heating of the magnetic bead-sample in cooperation with the heater. Claim 4. The system of claim 3, wherein the capture segment is an S-shaped capture segment, and wherein in an operation mode of the system the magnet is configured to cross a subset of the capture segment in a direction perpendicular to a flow direction through the capture segment thereby providing a magnetic field at the subset of the capture segment to capture the magnetic bead-sample within the capture Segment. Claim 8. The system of claim 1, further comprising a liquid handling system configured to transfer the magnetic bead sample from the capture plate to the molecular diagnostic module, and to aspirate the nucleic acid volume from the molecular diagnostic module. U.S. Patent No. 9,604,213 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of

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		<p>nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay Strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,604,213 at col. 3:28-35 (“The liquid handling system 250 then aspirates substantially all of each sample of the set of lysed biological samples combined with magnetic beads (i.e., set of magnetic bead samples) from the capture plate no, and dispenses the set of magnetic bead-samples into a microfluidic cartridge 210, aligned within a cartridge receiving module 140 of a molecular diagnostic module 130, and configured to be manipulated by the molecular diagnostic module 130.”) • U.S. Patent No. 9,604,213 at col. 3:62-66 (“As shown in FIGS. 3A and 3B, the capture plate 110 comprises a capture plate substrate in comprising a set of wells 112 and a puncturable foil seal 115, and functions to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119.”) • U.S. Patent No. 9,604,213 at col. 4:23-33 (“The set of wells 112 of the capture plate substrate in function to receive at least one biological sample which contain or are suspected of potentially containing nucleic acids, and to facilitate combination of the biological sample with a set of magnetic beads 119. Preferably, the wells 113 are each configured to accommodate not only a biological sample, but also to facilitate mixing of the biological sample with a set of magnetic beads 119 (e.g., using a pipettor, the liquid handling system 250 or other apparatus), which preferably are preloaded in wells 112, or alternatively may be added by an operator.”) <p>US1001888 (Exhibit 55)</p> <ul style="list-style-type: none"> • Claim 8. The system of claim 6, wherein the capture segment is an s-shaped capture segment, and wherein in an operation mode of the system the magnet is configured to cross a portion of the capture segment in a direction perpendicular to a flow direction through the capture segment thereby providing a magnetic field at the portion of the capture segment. • Claim 14: A method for processing and detecting nucleic acids from a sample with a cartridge including a fluidic pathway passing between a heating region of the cartridge and a magnet housing region of the cartridge, wherein the method comprises: with a liquid handling system, combining the sample with a quantity of magnetic beads to produce a nucleic acid-magnetic bead sample; with the liquid handling system, transferring the nucleic acid-magnetic bead sample to the fluidic pathway of the cartridge; and contemporaneously transmitting heat through the

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		<p>heating region, by way of a heater, and transmitting heat through the magnet housing region, by way of a magnet heating element coupled to a magnet, thereby facilitating capture of nucleic acids of the sample at the fluidic pathway of the cartridge.</p> <ul style="list-style-type: none"> • Claim 16. The method of claim 14, wherein transferring the nucleic acid-magnetic bead sample to the fluidic pathway of the cartridge comprises transferring the nucleic acid-magnetic bead sample into an s-shaped capture segment passing between the heating region and the magnet housing region of the cartridge. • U.S. Patent 10,010,888 at col. 4:29-39 (“The set of wells 112 of the capture plate substrate 111 function to receive at least one biological sample which contain or are suspected of potentially containing nucleic acids, and to facilitate combination of the biological sample with a set of magnetic beads 119. Preferably, the wells 113 are each configured to accommodate not only a biological sample, but also to facilitate mixing of the biological sample with a set of magnetic beads 119 (e.g., using a pipettor, the liquid handling system 250 or other apparatus), which preferably are preloaded in wells 112, or alternatively may be added by an operator.”) • U.S. Patent No. 10,010,888 at col. 6:15-29 (“An embodiment of the system 100 may further comprise a capture plate module 120, as shown in FIG. 4, which functions to receive, support, and heat a capture plate 110. The capture plate module 120 preferably comprises a thermally conducting substrate 121 configured to cradle a capture plate 110, a capture plate heater 123, a capture plate receiving module 125, and a capture plate electronics module 127. Preferably, the capture plate module 120 functions to facilitate lysis of a biological sample deposited into a well 113 of the capture plate, and to facilitate binding of nucleic acids (i.e., within a lysed biological sample) to a quantity of magnetic beads 119 within a well 113 of the capture plate 110. In a specific example, the capture plate module 120 has dimensions of 108 mmx156 mmx45 mm and is configured to rest on a flat surface.”) • U.S. Patent No. 10,010,888 at col. 30:45-64 (“An embodiment of a method 400 for processing and detecting nucleic acids from a set of biological samples comprises: combining each biological sample of the set of biological samples with a quantity of magnetic beads to produce a set of magnetic bead-sample mixtures S410; heating the set of magnetic bead-sample mixtures to produce a set of magnetic bead-samples S420; transferring a set of nucleic acid-magnetic bead samples S420; transferring each nucleic acid-magnetic bead sample of the set of nucleic-acid magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways S430; producing a set of nucleic acid volumes from the set of nucleic acid-magnetic bead samples S440; combining each nucleic acid volume of the set of nucleic acid volumes with a molecular diagnostic reagent of a set of molecular diagnostic reagents to produce a set of nucleic acid-reagent mixtures, through the corresponding fluidic pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers S460; and receiving light from the set of nucleic acid-reagent mixtures S470.”) • U.S. Patent No. 10,010,888 at col. 33:12-17 (“Step S430 recites transferring each nucleic acid-magnetic bead

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		<p>sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways, and functions to isolate each of the set of nucleic acid-magnetic bead samples within separate pathways for further processing.”)</p> <p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at 16:58 (“Thereafter in the first embodiment, as shown in FIG. 1E, the fluidic pathway 165 may be occluded at the second occlusion position 143 and the occlusion at the first occlusion 142 may be reversed, thus creating a third truncate pathway as shown in FIG. 1D. A release solution may then be delivered through the fluid port 118, into the capture segment 166, and to the waste chamber 130 by passing the fifth occlusion position 146. The release solution may then be sealed within a fourth truncated pathway (including the capture segment 166) of the fluidic pathway 165 by occluding the fluidic pathway at the fifth occlusion position 146, as shown in FIG. 1F. A release solution may then be delivered to other fluidic pathways of the set of fluidic pathways 160.”) <p>US9101930 (Exhibit 25)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,101,930 at col. 16 (“Thereafter in the first embodiment, as shown in FIG. 1E, the fluidic pathway 165 may be occluded at the second occlusion position 143 and the occlusion at the first occlusion 142 may be reversed, thus creating a third truncated pathway as shown in FIG. 1D. A release solution may then be delivered through the fluid port 118, into the capture segment 166, and to the waste chamber 130 by passing the fifth occlusion position 146. The release solution may then be sealed within a fourth truncated pathway (including the capture segment 166) of the fluidic pathway 165 by occluding the fluidic pathway at the fifth occlusion position 146, as shown in FIG. 1F. A release solution may then be delivered to other fluidic pathways of the set of fluidic pathways 160. <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at col. 16:38-50 (“Thereafter in the first embodiment, as shown in FIG. 1E, the fluidic pathway 165 may be occluded at the second occlusion position 143 and the occlusion at the first occlusion 142 may be reversed, thus creating a third truncated pathway as shown in FIG. 1D. A release solution may then be delivered through the fluid port 118, into the capture segment 166, and to the waste chamber 130 by passing the fifth occlusion position 146. The release solution may then be sealed within a fourth truncated pathway (including the capture segment 166) of the fluidic pathway 165 by occluding the fluidic pathway at the fifth occlusion position 146, as shown in FIG. 1F. A release solution may then be delivered to other fluidic pathways of the set of fluidic pathways 160.”)

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1(c)	wherein the retaining step comprises binding the polynucleotides to the surfaces of the plurality of the binding particles comprising a poly-cationic substance,	<p>The accused workflow comprises retaining polynucleotides from a sample on a plurality of binding particles in a process chamber under a first set of conditions, wherein the retaining step comprises binding the polynucleotides to the surfaces of the plurality of the binding particles comprising a poly-cationic substance.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <p>On information and belief, the accused system comprises retaining polynucleotides from a sample on a plurality of binding particles in a process chamber under a first set of conditions, wherein the retaining step comprises binding the polynucleotides to the surfaces of the plurality of the binding particles comprising a poly-cationic substance.</p> <ul style="list-style-type: none"> • “Liquid Handling Processing A: Lysis and Capture. Dispensing lysis buffer. Dispensing lysis buffer and patient specimen into extraction plate. The liquid handling robot delivers lysis buffer and patient specimen to the extraction plate, which has 24 independent wells which contain NeuDry affinity-coated paramagnetic beads. Each mixture is aspirated and dispensed five times to ensure homogeneity of the solution. During the transfer of patient specimen to the extraction plate the liquid handling robot uses pre-defined no-fly zones to reduce the potential of contamination.” <i>Id.</i> at 0:28-1:05 • <i>Id.</i> at 0:40 (showing the extraction plate).

Claim	Claim Language	Infringement Evidence
		<div><p>Downloaded on 3/26/2019</p></div> <ul style="list-style-type: none">• “Each extraction plate well is then autonomously heated for as little as six minutes to ensure proper lysing and binding of the nucleic acids to the paramagnetic beads. The temperatures applied range from 37° C to over 90° C, resulting in the flexibility to process a wide variety of DNA and RNA IVD and LDT tests simultaneously.” 1:07-1:32• <i>Id.</i> at 1:16 (showing binding of nucleic acids to paramagnetic beads). <div><p>Downloaded on 3/26/2019</p></div>

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		<p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> • “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieveing [sic] optimal operational and clinical performance for our customers and their patients.” • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents. <p>40500098_D-IFU-NeuMoDx-Extraction-Plate-US-ONLY (Exhibit 59)</p> <ul style="list-style-type: none"> • “Each 24-well NeuMoDx Extraction Plate contains dried, room-temperature stable reagents including proprietary coated magnetic microspheres, a lytic enzyme, and RNA and DNA Sample Process Controls. Components within the extraction plate work in conjunction with the appropriate NeuMoDx lysis buffer to lyse cells in a temperature dependent manner and bind the nucleic acid while reducing activity of any nucleases present in clinical samples. The Sample Process Controls bind to the magnetic microspheres at the same time as the target nucleic acid, and are carried throughout the extraction procedure, serving as internal controls to monitor for any inefficiencies in the extraction process and presence of PCR interference substances.” <i>Id.</i> at 1. • “The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate lysis buffer in the NeuMoDx Extraction Plate and is subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres.” <i>Id.</i> at 1. • “The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution.” <i>Id.</i> at 1.

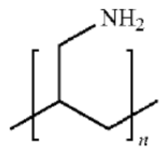
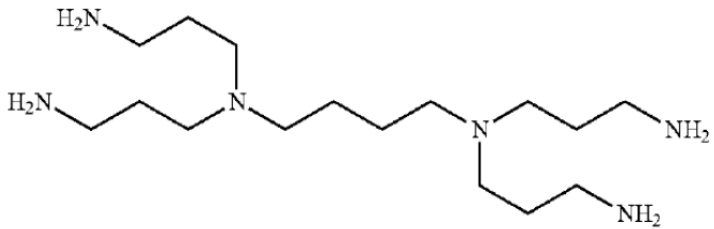
Claim	Claim Language	Infringement Evidence
		<p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound nucleic acid is eluted using the NeuMoDx™ RELEASE Solution. <p>40600100_-Rev-D-IFU-NeuMoDx-WASH-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 58)</p> <ul style="list-style-type: none"> The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 20)</p> <ul style="list-style-type: none"> The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600103_Rev-D-IFU-NeuMoDx-Lysis-Buffer-4-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 66)</p> <ul style="list-style-type: none"> The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the

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		<p>extracted nucleic acid for detection by Real-Time PCR. An aliquot of enriched Lim Broth is mixed with NeuMoDx Lysis Buffer 4 and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres dried in the NeuMoDx Extraction Plate.</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600104_ Rev-D-IFU-NeuMoDx-Lysis-Buffer-3-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 65)</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600105_ Rev-D-IFU-NeuMoDx-Lysis-Buffer-2-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 64)</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600106_ Rev-D-IFU-NeuMoDx-Lysis-Buffer-1-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 63)</p> <p>The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution.</p> <p>40600129_D-IFU-GBS-Test-Strip-US-only.pdf (Exhibit 60)</p> <ul style="list-style-type: none"> “NeuMoDx™ GBS Test Strip: Instructions for Use...The released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are loaded in to the NeuMoDx™ Cartridge where the unbound, non-DNA components are further washed away with NeuMoDx™ WASH Solution and the bound DNA is eluted using NeuMoDx™ RELEASE Solution.” <p>40600145_ -Rev-D-IFU-NeuMoD-LDT-Master-Mix-DNA-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 67)</p>

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • “NeuMoDx™ LDT Master Mix, DNA: Instructions for Use...Upon lysis, the released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound DNA is eluted using NeuMoDx™ RELEASE SOLUTION.” <p>40600146_D-IFU-NeuMoDx-LDT-Master-Mix-RNA-US-ONLY (Exhibit 62)</p> <ul style="list-style-type: none"> • “NeuMoDx™ LDT Master Mix, RNA: Instructions for Use...Upon lysis, the released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound RNA is eluted using NeuMoDx™ RELEASE Solution.” <p>US9339812 (Exhibit 26)</p> <ul style="list-style-type: none"> • Claim 18. The method of claim 15, wherein combining each biological sample of the set of biological samples with a quantity of magnetic beads comprises combining each biological sample of the set of biological samples with a quantity of magnetic beads treated to be at least one of positively charged, magnetic, paramagnetic, and supraparamagnetic [sic].” • U.S. Patent No. 9,339,812 at col: 4:42-49 (“The magnetic beads are preferably polymer beads, precoupled with a ligand for binding to a nucleic acid, and comprising a superparamagnetic [sic] component. Additionally, the magnetic beads may be treated to be positively charged. However, the magnetic beads may alternatively be any appropriate magnetic beads (e.g. magnetic, paramagnetic [sic], or superparamagnetic) configured to facilitate biomagnetic separation.”) • U.S. Patent No. 9,339,812 at col. 27:50-56 (“The magnetic beads are preferably polymer beads, precoupled with a ligand for binding to a nucleic acid, and comprising a Superparamagnetic component. Additionally, the magnetic beads may be treated to be positively charged. However, the magnetic beads may alternatively be any appropriate magnetic beads configured to facilitate biomagnetic separation.”) <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> • Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a

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		<p>biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 2. The method of claim 1, wherein receiving the binding moiety solution, comprising the set of affinity moiety-coated microparticles, within the process chamber comprises receiving a set of magnetic microparticles, each magnetic microparticle modified with an amine-reactive ester functional group configured to react with one of a set of amine groups of a molecule of Polypropylenimine tetramine dendrimer Generation 1. • Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the microfluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20 uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction. • Claim 19. A method for nucleic acid isolation from a biological sample, comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution includes a set of affinity moiety-coated

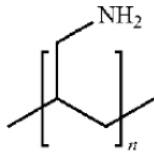
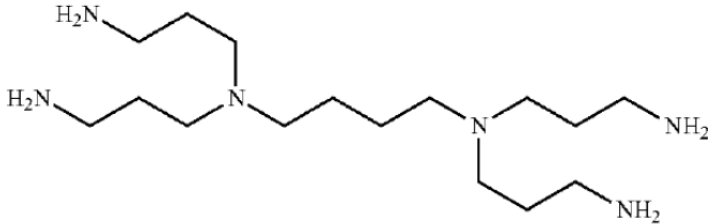
Claim	Claim Language	Infringement Evidence
		<p>microparticles, comprising a set of microparticles amide-bonded to at least one of poly(allylamine) of molecular weight <30,000 Da and Polypropylenimine tetramine dendrimer Generation 1; producing a moiety-sample mixture upon combination of the binding moiety solution with the biological sample; producing a set of moiety-bound nucleic acid particles upon incubation of the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of the set of pins includes reversing displacement of at least one pin of the first subset of the set of pins, and reversing occlusion of a portion of the fluidic pathway.</p> <ul style="list-style-type: none">• U.S. Patent No. 9,382,532 at 4:56-5:2 (“Step S120 recites mixing the binding moiety solution with a biological sample, within the process chamber, in order to produce a moiety-sample solution, which functions to initiate lysis of the biological sample and enable target nucleic acids to bind to affinity moieties of the binding moiety solution. Preferably, binding of target nucleic acids to affinity moieties is facilitated by the appropriate pH of the binding solution, as shown in FIG. 1C; however, binding can be facilitated by any other suitable mechanism. In a variation involving an appropriate pH in the binding solution, mixing and binding can occur at a low pH, which produces a positively charged affinity moiety that is attracted to negatively charged nucleic acid molecules. Specific examples of affinity moieties that function via a pH shift are described in Section 2 below.”)• U.S. Patent No. 9,382,532 at 9:9-30 (“In one variation of Step S160, the affinity moieties, examples of which are described in Section 2 below, function based upon the pH of the environment. Specifically, at low pH, the affinity moieties are positively charged, which results in attraction to negatively charged nucleic acids; however, at high pH, the affinity moieties are negatively charged, which results in repulsion of negatively charged nucleic acids. In a specific example of this variation, releasing the nucleic acid sample comprises providing an elution solution that is in the range of pH 12-pH 13 to effect efficient elution/release of the bound target nucleic acid(s) from the microparticle based upon a shift to a more basic pH. In the specific example, the elution solution comprises 20 mM of NaOH; however, in other variations the elution solution can comprise any other suitable concentration of NaOH or KOH, depending upon the application (e.g., sample type). Again, substantial removal of the wash solution during variations of the method 100 comprising Step S150 can facilitate or enhance the pH-shift for nucleic acid release, as the wash solution can potentially neutralize the elution solution in an undesirable manner and mitigate the elevated pH necessary

Claim	Claim Language	Infringement Evidence
		<p>for releasing the target nucleic acid(s).”)</p> <ul style="list-style-type: none">U.S. Patent No. 9,382,532 at 11:30-40 (“Nucleic acid molecules are typically negatively charged at standard processing conditions. In such processes, positively charged moieties can capture and retain the negatively charged nucleic acid molecules; however, the positively charged moieties can bind too strongly with target nucleic acids leading to an irreversible process whereby the bound nucleic acid cannot be released into the solution for further processing/analysis. Two novel molecules that are capable of binding nucleic acid in a reversible manner are described below, wherein the reversible binding is modulated by changing the pH of the environment.”)U.S. Patent No. 9,382,532 at 11:43-53 (“Poly(allylamine), or PAA, is a cationic poly electrolyte prepared by the polymerization of allylamine. Allylamine is an organic compound with the formula C3H5NH2 . An exemplary PAA <div data-bbox="1392 574 1553 721"></div> <p>molecule has the following formula: ”)</p> <ul style="list-style-type: none">U.S. Patent No. 9,382,532 at 12:11-27 (“Polypropylenimine tetramine dendrimer Generation 1, or DABAM Generation 1, is a cationic polyelectrolyte dendrimer. Dendrimers are repetitively branched molecules. A dendrimer is typically symmetric around a core, and often adopts a spherical three-dimensional structure. An exemplary DABAM <div data-bbox="1303 883 2016 1110"></div> <p>molecule has the following formula: ”)</p> <ul style="list-style-type: none">U.S. Patent No. 9,382,532 at 12:51-61 (“The affinity moieties, such as the PAA and DABAM described in Section 2.1 and 2.2, can be immobilized on a suitable substrate to facilitate subsequent capture of target nucleic acids bound to the substrate (e.g., by magnetic separation, size-based separation, density-based separation, or focusing). A process for coupling the affinity moiety to the substrate preferably relies on creation of a covalent bond between the affinity moiety and the microparticle, and in one variation as described below, a carboxylic acid group (-COOH) can be used to form the covalent bond between the microparticles and the affinity moieties.”U.S. Patent No. 9,382,532 at 12:62-13:13 (“As shown in FIG. 3, a method 200 for coupling the microparticles with

Claim	Claim Language	Infringement Evidence
		<p>the affinity moieties comprises activating carboxylated microparticles with EDAC 5210 to form a set of microparticle-reactive ester compounds; treating the set of microparticle-reactive ester compounds with an N-Hydroxysuccinimide to form a set of microparticle-amine reactive ester compounds S220, combining the set of microparticle-amine reactive ester compounds with a set of affinity moieties selected from the group comprising PAA and DABAM S230 to produce a microparticle-moiety solution; and washing the microparticle-moiety solution, thereby producing a set of microparticles covalently bonded to the set of affinity moieties by amide bonds S240. The method 200 functions to produce a set of moiety-bound microparticles for nucleic acid isolation. Preferably, the microparticles are magnetic to facilitate nucleic acid isolation by magnetic separation; however, the microparticles can alternatively be characterized by any suitable feature that facilitates nucleic acid isolation, as described earlier in Section 1.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at 13:14-28 (“In a specific example, as shown in FIG. 3, the method 200 comprises activating magnetic carboxylated microparticles with EDAC in Step S110 to form a set of magnetic microparticle-reactive ester compounds; treating the set of magnetic microparticle-reactive ester compounds with a N-Hydroxysulfosuccinimide to form a set of microparticle-amine reactive ester compounds S220; combining the set of microparticle-amine reactive ester compounds with a set of affinity moieties selected from the group comprising PAA of molecular weight less than 30,000 Da and DABAM of generation less than two S230 to produce a microparticle-moiety solution; and repeatedly washing the microparticle-moiety solution, thereby producing a set of magnetic microparticles covalently bonded to the set of affinity moieties by amide bonds S240.”) • U.S. Patent No. 9,382,532 at 13:42-45 (“A first example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, cerebrospinal fluid (CSF) as a representative biological sample, and Enterovirus (EV) viral particles as the model target.”) • U.S. Patent No. 9,382,532 at 14:5-9 (“A second example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, M4 transport medium containing a nasal swab (donor) as a representative biological sample, and Enterovirus (EV) viral particles as the model target.”) • U.S. Patent No. 9,382,532 at 14:41-45 (“A third example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, Universal Transport Medium (UTM) containing a nasal swab (donor) as a representative biological sample, and Enterovirus (EV) viral particles as the model target.”) • U.S. Patent No. 9,382,532 at 15:8-12 (“A fourth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, M4 transport medium containing nasal swab (donor) as a representative biological sample, and Enterovirus (EV) viral particles as the model target.”) • U.S. Patent No. 9,382,532 at 15:59-63 (“A fifth example of the method 100 comprises using DABAM affinity moieties coated onto magnetic microparticles, Human Urine (donor), Human Plasma and Buccal Swab (donor) as representative biological sample matrices, and Group B Streptococcus (GBS) DNA (ATCC, Virginia) as the model

Claim	Claim Language	Infringement Evidence
		<p>target.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at 16:29-32 (“A sixth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, Human Urine (donor) as a representative biological sample, and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,382,532 at 16:61-65 (“A seventh example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, Human Plasma (donor, obtained from Bioreclamation, Inc.) as a representative biological sample, and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,382,532 at 17:27-31 (“An eighth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, simulated swab specimens as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,382,532 at 17:60-64 (“A ninth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, simulated swab transport media specimens as representative biological samples and Group B Streptococcus (GBS) DNA at the model target.”) • U.S. Patent No. 9,382,532 at 18:31-34 (“A tenth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, whole blood as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,382,532 at 19:12-15 (“An eleventh example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, Urine (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,382,532 at 19:46-49 (“A twelfth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, plasma (donor) as a representative biological sample, and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,382,532 at 20:6-11 (“A thirteenth example of the method 100, demonstrating the effect of binding time, comprises using PAA affinity moieties coated onto magnetic microparticles, Human Plasma (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA (ATCC, Virginia) as the model target.”) • U.S. Patent No. 9,382,532 at 20:33-38 (“A fourteenth example of the method 100, demonstrating the effect of binding temperature, comprises using PAA affinity moieties coated onto magnetic microparticles, Human Plasma (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA (ATCC, Virginia) as the model target.”) • U.S. Patent No. 9,382,532 at 21:23-27 (“A fifteenth example of the method 100, demonstrating the effect of binding temperature, comprises using PAA affinity moieties coated onto magnetic microparticles, Urine (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,382,532 at 21:58-62 (“A sixteenth example of the method 100, demonstrating the use of two

Claim	Claim Language	Infringement Evidence
		<p>different elution solutions, comprises using PAA affinity moieties coated onto magnetic microparticles, Human Urine (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,382,532 at 22:31-37 (“A seventeenth example of the method 100, demonstrating the use of nucleic acid isolation reagents for total nucleic acid (TNA) extraction, comprises using PAA affinity moieties coated onto magnetic microparticles, M4 transport media as a representative biological sample, and Enterovirus (EV) viral particles as the model RNA target and Group B Streptococcus DNA as model DNA target.”) <p>US9540636 (Exhibit 54)</p> <ul style="list-style-type: none"> Claim 2. The method of claim 1, wherein the set of affinity moiety-coated microparticles comprises a set of magnetic microparticles, and wherein receiving the binding moiety solution, comprising the set of affinity moiety-coated microparticles, within the process chamber comprises receiving the set of magnetic microparticles, each magnetic microparticle modified with an amine-reactive ester functional group configured to react with one of a set of amine groups of a molecule of Polypropylenimine tetramine dendrimer Generation 1. Claim 19. The method of claim 17, wherein the set of affinity moiety-coated microparticles comprises a set of microparticles amide-bonded to at least one of the Poly(allylamine) of molecular weight <40,000 Da and the Polypropylenimine tetramine dendrimer Generation 1. U.S. Patent No. 9,540,636 at Abstract (“A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber; mixing the binding moiety solution with a biological sample, within the process chamber, in order to produce a moiety-sample mixture; incubating the moiety-sample mixture during a time window, thereby producing a solution comprising a set of moiety-bound nucleic acid particles and a waste volume; separating the set of moiety-bound nucleic acid particles from the waste volume; washing the set of moiety-bound nucleic acid particles; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles. The method preferably utilizes a binding moiety comprising at least one of poly(allylamine) and polypropylenimine tetramine dendrimer, both of which reversibly bind and unbind to nucleic acids based upon environmental pH.”) U.S. Patent No. 9,540,636 at col. 11:51-61 (“Nucleic acid molecules are typically negatively charged at standard processing conditions. In such processes, positively charged moieties can capture and retain the negatively charge nucleic acid molecules; however, the positively charged moieties can bind too strongly with target nucleic acids leading to an irreversible process whereby the bound nucleic acid cannot be released into the solution for further processing/analysis. Two novel molecules that are capable of binding nucleic acid in a reversible manner are described below, wherein the reversible binding is modulated by changing the pH of the environment.”) U.S. Patent No. 9,540,636 at col. 11:65-66 (“Poly(allylmine), or PAA, is a cationic polyelectrolyte prepared by the polymerization of allylamine.”)

Claim	Claim Language	Infringement Evidence
		<div><p>Chemical structure of a polypropylenimine dendrimer (DABAM) showing a repeating unit with an amine group.</p></div> <ul style="list-style-type: none">U.S. Patent No. 9,540,636 at col.12:36-38 (“Polypropylenimine tetramine dendrimer Generation 1, or DABAM Generation 1, is a cationic polyelectrolyte dendrimer.”) <div><p>Chemical structure of a polyamine molecule with four terminal amine groups.</p></div> <ul style="list-style-type: none">U.S. Patent No. 9,540,636 at col. 14:9-12 (A first example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, cerebrospinal fluid (CSF) as a representative biological sample, and Enterovirus (EV) viral particles as the model target.”)U.S. Patent No. 9,540,636 at col. 14:44-48 (“A second example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, M4 transport medium containing a nasal Swab (donor) as a representative biological sample, and Enterovirus (EV) viral particles as the model target.”)U.S. Patent No. 9,540,636 at col. 15:18-22 (“A third example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, Universal Transport Medium (UTM) containing a nasal swab (donor) as a representative biological sample, and Enterovirus (EV) viral particles as the model target.”)U.S. Patent No. 9,540,636 at col. 15:56-60 (“A fourth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, M4 transport medium containing nasal Swab (donor) as a representative biological sample, and Enterovirus (EV) viral particles as the model target.”)U.S. Patent No. 9,540,636 at col. 16:43-48 (“A fifth example of the method 100 comprises using DABAM affinity moieties coated onto magnetic microparticles, Human Urine (donor), Human Plasma and Buccal Swab (donor) as representative biological sample matrices, and Group B Streptococcus (GBS) DNA (ATCC, Virginia) as the model

Claim	Claim Language	Infringement Evidence
		<p>target.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 17:19-22 (“A sixth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, Human Urine (donor) as a representative biological sample, and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,540,636 at col. 17:56-60 (“A seventh example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, Human Plasma (donor, obtained from Bioreclamation, Inc.) as a representative biological sample, and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,540,636 at col. 18:26-31 (“An eighth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, simulated Swab specimens as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,540,636 at col. 18:65-19:2 (“A ninth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, simulated Swab transport media specimens as representative biological samples and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,540,636 at col. 19:41-44 (“A tenth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, whole blood as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,540,636 at col. 20:27-30 (“An eleventh example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, Urine (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,540,636 at col. 20:66-21:2 (“A twelfth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, plasma (donor) as a representative biological sample, and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,540,636 at col. 21:31-36 (“A thirteenth example of the method 100, demonstrating the effect of binding time, comprises using PAA affinity moieties coated onto magnetic microparticles, Human Plasma (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA (ATCC, Virginia) as the model target.”) • U.S. Patent No. 9,540,636 at col. 21:61-66 (“A fourteenth example of the method 100, demonstrating the effect of binding temperature, comprises using PAA affinity moieties coated onto magnetic microparticles, Human Plasma (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA (ATCC, Virginia) as the model target.”) • U.S. Patent No. 9,540,636 at col. 22:56-60 (“A fifteenth example of the method 100, demonstrating the effect of binding temperature, comprises using PAA affinity moieties coated onto magnetic microparticles, Urine (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target.”)

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none">• U.S. Patent No. 9,540,636 at col. 23:30-35 (“A sixteenth example of the method 100, demonstrating the use of two different elution solutions, comprises using PAA affinity moieties coated onto magnetic microparticles, Human Urine (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target.”)• U.S. Patent No. 9,540,636 at col. 24:10-16 (“A seventeenth example of the method 100, demonstrating the use of nucleic acid isolation reagents for total nucleic acid (TNA) extraction, comprises using PAA affinity moieties coated onto magnetic microparticles, M4 transport media as a representative biological sample, and Enterovirus (EV) viral particles as the model RNA target and Group B Streptococcus DNA as model DNA target.”)
1(d)	wherein the sample has a volume from 0.5 microliters to 3 milliliters;	<p>The accused workflow comprises retaining polynucleotides from a sample on a plurality of binding particles in a process chamber under a first set of conditions, wherein the retaining step comprises binding the polynucleotides to the surfaces of the plurality of the binding particles comprising a poly-cationic substance, wherein the sample has a volume from 0.5 microliters to 3 milliliters.</p> <p>40600145_-Rev-D-IFU-NeuMoD-LDT-Master-Mix-DNA-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 67)</p> <p>WARNINGS & PRECAUTIONS</p> <ul style="list-style-type: none">• This test is for in vitro diagnostic use with NeuMoDx Systems only.• Do not use the reagents after the listed expiration date.• Do not use any reagents if the safety seal is broken or if the packaging is damaged upon arrival.• Do not use reagents if the protective pouch is open or broken upon arrival.• Do not reuse any NeuMoDx consumable or reagent.• Minimum specimen volume is 1 mL; volume less than 1 mL may result in an instrument error. <p>40600146_D-IFU-NeuMoDx-LDT-Master-Mix-RNA-US-ONLY.pdf (Exhibit 62)</p>


Claim	Claim Language	Infringement Evidence
		<p>WARNINGS & PRECAUTIONS</p> <ul style="list-style-type: none">• This test is for in vitro diagnostic use with NeuMoDx Systems only.• Do not use the reagents after the listed expiration date.• Do not use any reagents if the safety seal is broken or if the packaging is damaged upon arrival.• Do not use reagents if the protective pouch is open or broken upon arrival.• Do not reuse any NeuMoDx consumable or reagent.• Minimum specimen volume is 1 mL; volume less than 1 mL may result in an instrument error. <p>NeuMoDx_EBV_Poster_AMP2018_FNL.pdf (Exhibit 82)</p> <ul style="list-style-type: none">• “Performance of the NeuMoDx EBV Test was characterized in both plasma and whole blood matrices. The objective of this study was to test and report performance of the NeuMoDx EBV Test across key analytical metrics. Studies were performed to characterize the analytical sensitivity, limits of quantitation, linearity, precision, turnaround time, and equivalency across specimen types. Testing was performed using either a 550 µL sample of plasma or a 220 µL sample volume of whole blood specimen.” <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none">• Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles

Claim	Claim Language	Infringement Evidence														
		<p>from the moiety-sample mixture, within the microfluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20 uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction.</p> <ul style="list-style-type: none">• U.S. Patent No. 9,382,532 at col. 5:16-24 (“Furthermore, in other variations, the moiety-sample solution can be transferred to any other suitable fluid vessel for mixing. In a specific example, between 5 uL-2 mL of biological sample is delivered to the process chamber containing the binding moiety solution and the resulting moiety-sample solution is then mixed thoroughly by aspirating and dispensing the moiety-sample solution ten times to ensure uniform distribution within the moiety-sample solution.”)• U.S. Patent No. 9,382,532 at col. 9:1-8 (“For example, the target nucleic acid(s) from 0.5 mL of an initial biological sample (undiluted by collection buffer) can be processed using the method 100 and eluted into ~10 uL of elution solution. In other examples, elution solution Volumes can be as low as 5 microliters resulting in a significant (50X-100x) concentration of the target nucleic acid from the initial biological sample.”)														
1(e)	wherein the first set of conditions includes a first pH of about 8.5 or less and a first temperature,	<p>The accused workflow comprises retaining polynucleotides from a sample on a plurality of binding particles in a process chamber under a first set of conditions, wherein the retaining step comprises binding the polynucleotides to the surfaces of the plurality of the binding particles comprising a poly-cationic substance, wherein the sample has a volume from 0.5 microliters to 3 milliliters, wherein the first set of conditions includes a first pH of about 8.5 or less and a first temperature.</p> <p>40600175 REV-C-SDS-NeuMoDx-Lysis-Buffer-1-Final.pdf (Exhibit 68)</p> <table><tr><td colspan="2">9.1 General Information</td></tr><tr><td>Form:</td><td>Liquid</td></tr><tr><td>Color:</td><td>Clear, with a slightly yellow tinge</td></tr><tr><td>Odor:</td><td>odorless</td></tr><tr><td>Odor Threshold:</td><td>Not determined</td></tr><tr><td>pH Value at 20°C (68°F):</td><td>4.45 – 4.9</td></tr><tr><td>Melting point/melting range:</td><td>Not determined</td></tr></table> <p>40600176 Rev-C-SDS -NeuMoDx-Lysis-Buffer-2-Final.pdf (Exhibit 69)</p>	9.1 General Information		Form:	Liquid	Color:	Clear, with a slightly yellow tinge	Odor:	odorless	Odor Threshold:	Not determined	pH Value at 20°C (68°F):	4.45 – 4.9	Melting point/melting range:	Not determined
9.1 General Information																
Form:	Liquid															
Color:	Clear, with a slightly yellow tinge															
Odor:	odorless															
Odor Threshold:	Not determined															
pH Value at 20°C (68°F):	4.45 – 4.9															
Melting point/melting range:	Not determined															

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		<div><div>9.1General Information</div><div><div>Form:</div><div>Color:</div><div>Odor:</div><div>Odor Threshold:</div><div>pH Value at 20°C (68°F):</div><div>Melting point/melting range:</div></div><div><div>Liquid</div><div>Clear, with a slightly yellow tinge</div><div>odorless</div><div>Not determined</div><div>4.2 – 5.2</div><div>Not determined</div></div></div> <div>40600177_Rev-C-SDS-NeuMoDx-Lysis-Buffer-3-Final.pdf (Exhibit 70)</div> <div><div>9.1General Information</div><div><div>Form:</div><div>Color:</div><div>Odor:</div><div>Odor Threshold:</div><div>pH Value at 20°C (68°F):</div><div>Melting point/melting range:</div></div><div><div>Liquid</div><div>Clear, with a slightly yellow tinge</div><div>Odorless</div><div>Not determined</div><div>4.9 – 5.1</div><div>Not determined</div></div></div> <div>40600112_Rev-B-SDS-NeuMoDx-Lysis-Buffer-4-FINAL.pdf (Exhibit 71)</div> <div><div>9.1General Information</div><div><div>Form:</div><div>Color:</div><div>Odor:</div><div>Odor Threshold:</div><div>pH Value at 20°C (68°F):</div><div>Melting point/melting range:</div></div><div><div>Liquid</div><div>Clear, with a slightly yellow tinge</div><div>odorless</div><div>Not determined</div><div>4.45 – 4.9</div><div>Not determined</div></div></div> <div>US9382532 (Exhibit 52)</div> <div><div><div>• U.S. Patent No. 9,382,532 at col. 3:35-43 (“The method 100 can be performed in any container or process chamber that is configured to contain a suitable concentration of affinity moiety-coated microparticles, facilitate suitable buffer conditions to allow for binding (e.g., buffer conditions providing a suitably low pH), contain suitable amounts of proteolytic or other enzymes for effective lysis or removal of inhibitory substances, and provide suitable ther-mal conditions that collectively enable binding of nucleic acids to the affinity moiety-coated microparticles.”)</div><div>• U.S. Patent No. 9,382,532 at 17:27-37 (“An eighth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, simulated Swab specimens as a representative biological sample and Group B</div></div></div> </

Claim	Claim Language	Infringement Evidence
		<p>Streptococcus (GBS) DNA as the model target. In the eighth example, a buccal Swab (obtained from a donor) was added to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg. Proteinase K and then spiked with 10 pg of GBS DNA in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37C in an example of Step S130.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at col. 28:49-51 (“CBD-1 (SP1: ultrapure water (93.1 mL), 1 M Tris pH 7.0 (50 mL), sodium citrate (50.88 g), boric acid (1.24 g), 0.5M EDTA pH 8.0 (2 mL), and Triton-X 100 (10 mL).”) • U.S. Patent No. 9,382,532 at col. 17:60-18:8 (“A ninth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, simulated Swab transport media specimens as representative biological samples and Group B Streptococcus (GBS) DNA as the model target. In the ninth example 500 uL of M4 Transport Media (M4) or Universal Transport Media (UTM) containing a buccal Swab (obtained from a donor) was spiked with 10pg of GBS DNA and then mixed with 500 uL of DNA Collection Buffer 3 (CBD-3) and 0.4 mg of Proteinase K in examples of Steps S110 and S120. For comparison, “Dry Swab’ samples were prepared by adding a buccal swab to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg Proteinase K and then spiked with 10 pg of GBS DNA. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37C in an example of Step S130.”) • U.S. Patent No. 9,382,532 at col. 28:55-57 (“CBD-3 ISP3: ultrapure water (862 mL), 1 M Tris pH 7.0 (100 mL), sodium citrate (11.76 g), boric acid (2.48 g), 0.5M EDTA pH 8.0 (4 mL), and Triton-X 100 (20 mL).”) • U.S. Patent 9,382,532 at col. 18:34-41 (“In the tenth example, 100 uL whole blood (donor, obtained from Bioreclamation, Inc.) was added to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg. Proteinase K and then spiked with 10pg of GBS DNA in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37 C in an example of Step S130.”) • U.S. Patent No. 9,382,532 at col. 21:27-33 (“In the fifteenth example, 500 uL of Urine (obtained from a donor) was spiked with mpg of GBS DNA and then mixed with 500 uL of DNA Collection Buffer 2 (CBD-2) in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature, 37 C, 45C, or 60 C in examples of Step S130.”) • U.S. Patent No. 9,382,532 at col. 28:52-54 (“CBD-2 SP2: ultrapure water (480 mL), 1 M Tris pH 7.0 (100 mL), sodium citrate (11.76 g), boric acid (2.48 g), 0.5M EDTA pH 8.0 (400 mL), and Triton-X 100 (20 mL).”) • U.S. Patent No. 9,382,532 at col. 22:37-43 (“In the seventeenth example, 500 uL of M4 was spiked with ten-fold serial dilutions of 1 uL of EV viral particle lysate and 1 uL of GBSDNA and then mixed with 500 uL of RNA Collection Buffer 3 (CBR-3) in examples of Steps S110 and S120. RNA and DNA were allowed to bind to the PAA affinity moieties for 10 minutes at 37 C in an example of Step S130.”) • U.S. Patent No. 9,382,532 at col. 28:46-48 (“CBR-3 2x EDTA only Buffer: ultrapure water (560 mL), 1M Tris pH 8.0

Claim	Claim Language	Infringement Evidence
		<p>(20 mL), 0.5M EDTA pH 8.0 (400 mL), and Triton-X 100 (20 mL).”)</p> <p>US9540636 (Exhibit 54)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 18:31-37 (“In the eighth example, a buccal Swab (obtained from a donor) was added to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg. Proteinase K and then spiked with 10 pg of GBS DNA in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37 C in an example of Step S130.”) • U.S. Patent No. 9,540,636 at col. 30:45-47 (“CBD-1 (SP1: ultrapure water (93.1 mL), 1 M Tris pH 7.0 (50 mL), sodium citrate (5.88 g), boric acid (1.24 g), 0.5M EDTA pH 8.0 (2 mL), and Triton-X 100 (10 mL).”) • U.S. Patent No. 9,540,636 at col. 19:2-13 (“In the ninth example 500 uL of M4 Transport Media (M4) or Universal Transport Media (UTM) containing a buccal Swab (obtained from a donor) was spiked with 10 pg of GBS DNA and then mixed with 500 uL of DNA Collection Buffer 3 (CBD-3) and 0.4 mg of Proteinase K in examples of Steps S110 and S120. For comparison, “Dry Swab’ samples were prepared by adding a buccal swab to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg. Proteinase K and then spiked with 10 pg of GBS DNA. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37 C in an example of Step S130.”) • U.S. Patent No. 9,540,636 at col. 30:51-53 (“CBD-3 ISP3: ultrapure water (862 mL), 1 M Tris pH 7.0 (100 mL), sodium citrate (11.76 g), boric acid (2.48 g), 0.5M EDTA pH 8.0 (4 mL), and Triton-X 100 (20 mL).”) • U.S. Patent No. 9,540,636 at col. 19:44-50 (“In the tenth example, 100 uL whole blood (donor, obtained from Bioreclamation, Inc.) was added to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg. Proteinase K and then spiked with 10 pg of GBS DNA in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37 C in an example of Step S130.”) • U.S. Patent No. 9,540,636 at col. 22:60-67 (“In the fifteenth example, 500 uL of Urine (obtained from a donor) was spiked with 10 pg of GBS DNA and then mixed with 500 uL of DNA Collection Buffer 2 (CBD-2) in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature, 37 C, 45 C, or 60 C in examples of Step S130.”) • U.S. Patent No. 9,540,636 at col. 30:48-50 (“CBD-2 SP2: ultrapure water (480 mL), 1 M Tris pH 7.0 (100 mL), sodium citrate (11.76 g), boric acid (2.48 g), 0.5M EDTA pH 8.0 (400 mL), and Triton-X 100 (20 mL).”) • U.S. Patent No. 9,540,636 at col. 23:16-22 (“In the seventeenth example, 500 uL of M4 was spiked with ten-fold serial dilutions of 1 uL of EV viral particle lysate and 1 LL of GBS DNA and then mixed with 500 uL of RNA Collection Buffer 3 (CBR-3) in examples of Steps S110 and S120. RNA and DNA were allowed to bind to the PAA affinity moieties for 10 minutes at 37C in an example of Step S130.”)


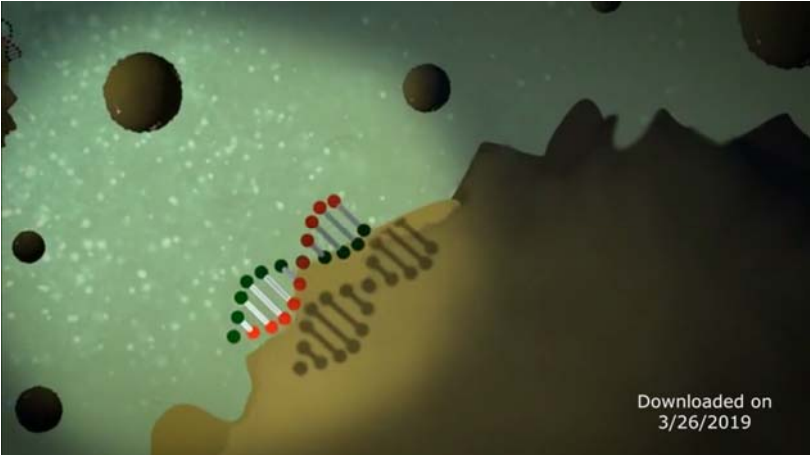
Claim	Claim Language	Infringement Evidence
1(f)	wherein the first temperature is between about 30° C and about 50° C;	<p>The accused workflow comprises retaining polynucleotides from a sample on a plurality of binding particles in a process chamber under a first set of conditions, wherein the retaining step comprises binding the polynucleotides to the surfaces of the plurality of the binding particles comprising a poly-cationic substance, wherein the sample has a volume from 0.5 microliters to 3 milliliters, wherein the first set of conditions includes a first pH of about 8.5 or less and a first temperature, wherein the first temperature is between about 30° C and about 50° C.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none">• “Liquid Handling Processing A: Lysis and Capture. Dispensing lysis buffer. Dispensing lysis buffer and patient specimen into extraction plate. The liquid handling robot delivers lysis buffer and patient specimen to the extraction plate, which has 24 independent wells which contain NeuDry affinity-coated paramagnetic beads. Each mixture is aspirated and dispensed five times to ensure homogeneity of the solution. During the transfer of patient specimen to the extraction plate the liquid handling robot uses pre-defined no-fly zones to reduce the potential of contamination.” <i>Id.</i> at 0:28-1:05• <i>Id.</i> at 0:40 (showing the extraction plate)  <p>On information and belief, the accused system comprises retaining polynucleotides from a sample on a plurality of binding particles in a process chamber under a first set of conditions, wherein the retaining step comprises binding the polynucleotides to the surfaces of the plurality of the binding particles comprising a poly-cationic</p>

Claim	Claim Language	Infringement Evidence
		<p>substance, wherein the sample has a volume from 0.5 microliters to 3 milliliters, wherein the first set of conditions includes a first pH of about 8.5 or less and a first temperature, wherein the first temperature is between about 30° C and about 50° C.</p> <ul style="list-style-type: none"> • “Each extraction plate well is then heated independently for 10 minutes to ensure proper lysing and binding of the nucleic acids to the paramagnetic beads. The temperatures applied range from 37 degrees Celsius to 60 degrees Celsius, resulting in the flexibility to process a wide variety of DNA and RNA IVD and LDT tests simultaneously.” <i>Id.</i> at 1:05-1:35 <p>40500098_D-IFU-NeuMoDx-Extraction-Plate-US-ONLY (Exhibit 59)</p> <ul style="list-style-type: none"> • “The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate lysis buffer in the NeuMoDx Extraction Plate and is subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres.” <i>Id.</i> at 1. <p>40600100_-Rev-D-IFU-NeuMoDx-WASH-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 58)</p> <ul style="list-style-type: none"> • The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. <p>40600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 20)</p> <ul style="list-style-type: none"> • The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. <p>40600103_Rev-D-IFU-NeuMoDx-Lysis-Buffer-4-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 66)</p> <ul style="list-style-type: none"> • The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic

Claim	Claim Language	Infringement Evidence
		<p>acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of enriched Lim Broth is mixed with NeuMoDx Lysis Buffer 4 and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres dried in the NeuMoDx Extraction Plate.</p> <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> • Claim 4: The method of claim 3, wherein incubating the moiety-sample mixture comprises heating the moiety-sample solution to a temperature in the range of 25-95°C for 5-60 minutes, thus simultaneously lysing the biological sample and facilitating binding of nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles. • U.S. Patent No. 9,382,532 at 17:27-37 (“An eighth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, simulated Swab specimens as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target. In the eighth example, a buccal Swab (obtained from a donor) was added to 1 mL of DNA Collection Buffer 1 (CBD 1) containing 0.4 mg. Proteinase K and then spiked with 10 pg of GBS DNA in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37C in an example of Step S130.”) • U.S. Patent No. 9,382,532 at col. 17:60-18:8 (“A ninth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, simulated Swab transport media specimens as representative biological samples and Group B Streptococcus (GBS) DNA as the model target. In the ninth example 500 uL of M4 Transport Media (M4) or Universal Transport Media (UTM) containing a buccal Swab (obtained from a donor) was spiked with 10pg of GBS DNA and then mixed with 500 uL of DNA Collection Buffer 3 (CBD-3) and 0.4 mg of Proteinase K in examples of Steps S110 and S120. For comparison, ‘Dry Swab’ samples were prepared by adding a buccal swab to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg Proteinase K and then spiked with 10 pg of GBS DNA. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37C in an example of Step S130.”) • U.S. Patent No. 9,382,532 at col. 28:55-57 (“CBD-3 ISP3: ultrapure water (862 mL), 1 M Tris pH 7.0 (100 mL), sodium citrate (11.76 g), boric acid (2.48 g), 0.5M EDTA pH 8.0 (4 mL), and Triton-X 100 (20 mL).”) • U.S. Patent 9,382,532 at col. 18:34-41 (“In the tenth example, 100 uL whole blood (donor, obtained from Bioreclamation, Inc.) was added to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg. Proteinase K and then spiked with 10pg of GBS DNA in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37 C in an example of Step S130.”)

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> U.S. Patent No. 9,382,532 at col. 21:27-33 (“In the fifteenth example, 500 uL of Urine (obtained from a donor) was spiked with mpg of GBS DNA and then mixed with 500 uL of DNA Collection Buffer 2 (CBD-2) in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature, 37 C, 45C, or 60 C in examples of Step S130.”) U.S. Patent No. 9,382,532 at col. 28:52-54 (“CBD-2 SP2: ultrapure water (480 mL), 1 M Tris pH 7.0 (100 mL), sodium citrate (11.76 g), boric acid (2.48 g), 0.5M EDTA pH 8.0 (400 mL), and Triton-X 100 (20 mL).”) U.S. Patent No. 9,382,532 at col. 22:37-43 (“In the seventeenth example, 500 uL of M4 was spiked with ten-fold serial dilutions of 1 uL of EV viral particle lysate and 1 uL of GBSDNA and then mixed with 500 uL of RNA Collection Buffer 3 (CBR-3) in examples of Steps S110 and S120. RNA and DNA were allowed to bind to the PAA affinity moieties for 10 minutes at 37 C in an example of Step S130.”) U.S. Patent No. 9,382,532 at col. 28:46-48 (“CBR-3 2x EDTA only Buffer: ultrapure water (560 mL), 1M Tris pH 8.0 (20 mL), 0.5M EDTA pH 8.0 (400 mL), and Triton-X 100 (20 mL).”) <p>US9540636 (Exhibit 54)</p> <ul style="list-style-type: none"> Claim 6: The method of claim 3, wherein incubating the moiety-sample mixture comprises heating the moiety-sample solution to a temperature above 25° C for at least 5 minutes, thus simultaneously lysing the biological sample and facilitating the binding of nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles. U.S. Patent No. 9,540,646 at col. 6:2-9 (“Preferably, the process chamber containing the moiety-sample solution (e.g., lysis, clean-up, binding reagents and the biological sample) is incubated for a defined period of time at a temperature preferably in the range of 25-95 C, wherein time and temperature parameters are biological sample-dependent. Example parameters for different biological samples are described briefly below, and further in Section 3 below.”) U.S. Patent No. 9,540,646 at col.6:24-31 (“In a variation of the first example, enteroviral particles treated with Proteinase K can be incubated and lysed within a modified temperature range of 37-60C for optimal activity of the proteinase enzyme. In a second example of Step S130, a nasal Swab containing Staphylococcus aureus bacteria is incubated at approximately 95 C to ensure thorough lysis of the gram-positive bacteria.”) U.S. Patent No. 9,540,636 at col. 18: 31-37 (“In the eighth example, a buccal Swab (obtained from a donor) was added to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg. Proteinase K and then spiked with 10 pg of GBS DNA in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37 C in an example of Step S130.”) U.S. Patent No. 9,540,636 at col. 30:45-47 (“CBD-1 (SP1: ultrapure water (93.1 mL), 1 M Tris pH 7.0 (50 mL), sodium citrate (5.88 g), boric acid (1.24 g), 0.5M EDTA pH 8.0 (2 mL), and Triton-X 100 (10 mL).”)

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> U.S. Patent No. 9,540,636 at col. 19:2-13 (“In the ninth example 500 uL of M4 Transport Media (M4) or Universal Transport Media (UTM) containing a buccal Swab (obtained from a donor) was spiked with 10 pg of GBS DNA and then mixed with 500 uL of DNA Collection Buffer 3 (CBD-3) and 0.4 mg of Proteinase K in examples of Steps S110 and S120. For comparison, “Dry Swab’ samples were prepared by adding a buccal swab to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg. Proteinase K and then spiked with 10 pg of GBS DNA. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37 C in an example of Step S130.”) U.S. Patent No. 9,540,636 at col. 19:44-50 (“In the tenth example, 100 uL whole blood (donor, obtained from Bioreclamation, Inc.) was added to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg. Proteinase K and then spiked with 10 pg of GBS DNA in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37 C in an example of Step S130.”) U.S. Patent No. 9,540,636 at col. 30:48-50 (“CBD-2 SP2: ultrapure water (480 mL), 1 M Tris pH 7.0 (100 mL), sodium citrate (11.76 g), boric acid (2.48 g), 0.5M EDTA pH 8.0 (400 mL), and Triton-X 100 (20 mL).”) U.S. Patent No. 9,540,636 at col. 24:16-22 (“In the seventeenth example, 500 uL of M4 was spiked with ten-fold serial dilutions of 1 uL of EV viral particle lysate and 1 LL of GBS DNA and then mixed with 500 uL of RNA Collection Buffer 3 (CBR-3) in examples of Steps S110 and S120. RNA and DNA were allowed to bind to the PAA affinity moieties for 10 minutes at 37C in an example of Step S130.”)
1(g)	releasing the polynucleotide from the plurality of binding particles under a second set of conditions; and	<p>The accused workflow comprises releasing the polynucleotide from the plurality of binding particles under a second set of conditions.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “A high pH NeuMoDx release reagent is dispensed into the S channel to cover the beads and heat is applied to complete the denaturation process, resulting in released nucleic acid or eluent.” 2:55-58 2:58 Release reagent

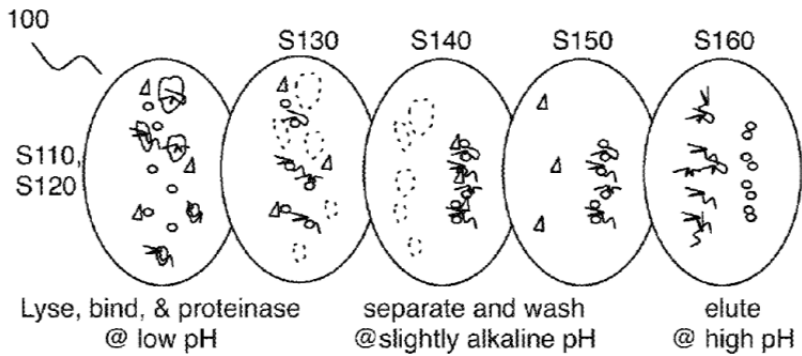
Claim	Claim Language	Infringement Evidence
		<div></div> <ul style="list-style-type: none">• 3:04 Heat/denaturation <div></div> <ul style="list-style-type: none">• “A precise volume of air is then applied to remove any remaining liquid into the waste chamber. NeuMoDx wash solution is pumped via the fluid port into the microfluidic cartridge to remove all unbound material, followed by another volume of air to remove excess wash solution. High pH NeuMoDx release reagent is dispensed into the s-channel to cover the beads, and heat is applied to the denaturation process, resulting in released nucleic acid or eluate.” <i>Id.</i> at 2:39-3:12.

Claim	Claim Language	Infringement Evidence
		<p>40600146_D-IFU-NeuMoDx-LDT-Master-Mix-RNA-US-ONLY (Exhibit 62)</p> <ul style="list-style-type: none"> “NeuMoDx™ LDT Master Mix, RNA Instructions for Use...Upon lysis, the released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound RNA is eluted using NeuMoDx™ RELEASE Solution.” <p>40600145_-Rev-D-IFU-NeuMoD-LDT-Master-Mix-DNA-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 67)</p> <ul style="list-style-type: none"> “NeuMoDx™ LDT Master Mix, DNA Instructions for Use...Upon lysis, the released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound DNA is eluted using NeuMoDx™ RELEASE Solution.” <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> “NeuMoDx™ Cartridge Instructions for Use...The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound nucleic acid is eluted using the NeuMoDx™ RELEASE Solution.” <p>40600129_D-IFU-GBS-Test-Strip-US-only.pdf (Exhibit 60)</p> <ul style="list-style-type: none"> “NeuMoDx™ GBS Test Strip Instructions for Use...The released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are loaded in to the NeuMoDx™ Cartridge where the unbound, non-DNA components are further washed away with NeuMoDx™ WASH Solution and the bound DNA is eluted using NeuMoDx™ RELEASE Solution.” <p>40600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018 (Exhibit 20)</p> <ul style="list-style-type: none"> “NeuMoDx™ Release Reagent Instructions for Use...NeuMoDx™ Release Reagent is a proprietary reagent that releases captured nucleic acid from NeuMoDx™ proprietary affinity magnetic microspheres providing the eluate at the proper pH for mixing the dried reagents in a NeuMoDx™ test strip and subsequent Real-Time PCR.” <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well

Claim	Claim Language	Infringement Evidence
		<p>configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at col. 10:49-52 (“The cartridge heater 153 functions to transfer heat to a heating region 224 of a microfluidic cartridge 210, for inducing a pH shift to release bound nucleic acids from magnetic beads within the heating region 224.”) • U.S. Patent 9,050,594 at col. 29:57-30:7 (“Preferably, Step S443 comprises defining at least one truncated fluidic pathway coupled to a waste chamber and to a fluid port, which functions to facilitate washing of at least one nucleic acid-magnetic bead sample in the set of nucleic acid-magnetic bead samples, and releasing of at least one nucleic acid volume from the set of nucleic acid-magnetic bead samples. Step S440 may additionally comprise delivering a wash solution through a portion of at least one fluidic pathway S444, such as the truncated fluidic pathway defined in Step S443, and delivering a release solution through a portion of at least one fluidic pathway S445, such as the truncated fluidic pathway defined in Step S443. Step S444 functions to wash at least one nucleic acid-magnetic bead sample in the set of nucleic acid-magnetic bead samples, and Step S445 functions to release at least one nucleic acid volume from the set of nucleic acid-magnetic bead samples. The heater provided in Step S442 may be activated after Step S445 to induce a pH shift.”) <p>US9339812 (Exhibit 26)</p> <ul style="list-style-type: none"> • Claim 7. The method of claim 6, wherein separating the volume of nucleic acids from the biological sample further comprises dispensing a release solution through the fluidic pathway by the fluid port. • Claim 8. The method of claim 7, wherein separating the volume of nucleic acids from the biological sample further comprises heating the first portion of the fluidic pathway to facilitate a pH shift, thus releasing nucleic acids from magnetic beads to produce the volume of nucleic acids. • Claim 20. The method of claim 19, wherein producing the set of nucleic acid volumes from the set of nucleic acid-magnetic bead samples comprises: upon passing a magnet through one of the set of slots of the cartridge platform of the molecular diagnostic module, providing a magnetic field spanning a portion of each fluidic pathway in the set of

Claim	Claim Language	Infringement Evidence
		<p>fluidic pathways, thus capturing the set of nucleic acid-magnetic bead samples; dispensing a wash solution into each fluidic pathway of the set of fluidic pathways; dispensing a release solution into each fluidic pathway of the set of fluidic pathways; and heating each fluidic pathway of the set of fluidic pathways to facilitate a pH shift, thus unbinding nucleic acids from magnetic beads to produce the set of nucleic acid volumes.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,339,812 at col. 10:49-52 (“The cartridge heater functions to transfer heat to a heating region of a microfluidic cartridge, for inducing a pH shift to release bound nucleic acids from magnetic beads within the heating region 224.”) • U.S. Patent NO. 9,339,812 at col. 25:43-49 (“The syringe pump 265 of the liquid handling system 250 is coupled to a wash solution source 266, a release solution source 267, a source of air 268, and flexible tubing 291, and functions to deliver a wash solution, a release solution, and air through a valve to the molecular diagnostic module 130 to facilitate isolation and purification of nucleic acids from a set of magnetic bead-samples.”) • U.S. Patent No. 9,339,812 at col. 29:50-53 (“Step S442 functions to provide a heater, which, in combination with a release solution that provides a pH shift, facilitate a rapid and efficient unbinding of the nucleic acids from magnetic beads.”) <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> • Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10. • Claim 12. The method of claim 1, further comprising releasing a nucleic acid sample from the set of moiety-bound

Claim	Claim Language	Infringement Evidence
		<p>nucleic acid particles, wherein releasing the nucleic acid sample comprises contacting the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH that is greater than pH 10.</p> <ul style="list-style-type: none">• Claim 13: The method of claim 3, wherein releasing the nucleic acid sample from the set of moiety-bound nucleic acid particles comprises occluding the fluidic pathway of the cartridge, comprising the process chamber, at a set of occlusion positions, upon displacement of pins of the set of pins, to define a path through a magnetic field; delivering the set of moiety-bound nucleic acid particles into the path of the fluidic pathway; and delivering an elution solution into the fluidic pathway, thereby inducing a pH shift configured to release the nucleic acid sample from the set of moiety-bound nucleic acid particles.”• Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the microfluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20 uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction.

Claim	Claim Language	Infringement Evidence
		<div data-bbox="801 256 1602 609"></div> <p data-bbox="1131 667 1298 699">FIGURE 1C</p> <ul style="list-style-type: none">U.S. Patent No. 9,382,532 at col. 9:9-24 (“In one variation of Step S160, the affinity moieties, examples of which are described in Section 2 below, function based upon the pH of the environment. Specifically, at low pH, the affinity moieties are positively charged, which results in attraction to negatively charged nucleic acids; however, at high pH, the affinity moieties are negatively charged, which results in repulsion of negatively charged nucleic acids. In a specific example of this variation, releasing the nucleic acid sample comprises providing an elution solution that is in the range of pH 12-pH 13 to effect efficient elution/release of the bound target nucleic acid(s) from the microparticle based upon a shift to a more basic pH. In the specific example, the elution solution comprises 20 mM of NaOH; however, in other variations the elution Solution can comprise any other suitable concentration of NaOH or KOH, depending upon the application (e.g., sample type).”)U.S. Patent No. 9,382,532 at col. 9:38-49 (“Preferably, an elevated temperature in combination with an elevated pH resulting from the elution solution provides the enhanced conditions to facilitate the release of the nucleic acid sample. Furthermore, an elevated temperature (e.g., elevating a sample eluted at room temperature to 85 C) can function to minimize protease enzyme activity in the eluted nucleic acid and thereby improve the robustness of the detection of the target nucleic acid sample during processing in variations of Step S110; however, the method 100 can alternatively omit Step S161 in applications wherein heating the moiety-bound nucleic acid Volume is undesirable and/or unnecessary.”) <p data-bbox="688 1344 1005 1377">US9540636 (Exhibit 54)</p> <ul style="list-style-type: none">Claim 17: A method for nucleic acid isolation from a biological sample, comprising: receiving a binding moiety

Claim	Claim Language	Infringement Evidence
		<p>solution within a process chamber, wherein the binding moiety solution includes a set of affinity moiety-coated microparticles; producing a moiety-sample mixture upon combination of the binding moiety solution with the biological sample; producing a set of moiety-bound nucleic acid particles upon incubation of the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the et of affinity moiety-coated microparticles; occluding a fluidic pathway of a cartridge upon displacement of a first subset of pin at the cartridge comprising the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles, within the fluidic pathway of the cartridge; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution.</p> <ul style="list-style-type: none"> • Claim 12. The method of claim 1, further comprising releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles, wherein releasing the nucleic acid sample comprises contacting the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH that is greater than pH 10. • Claim 17: A method for nucleic acid isolation from a biological sample, comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution includes a set of affinity moiety-coated microparticles; producing a moiety-sample mixture upon combination of the binding moiety solution with the biological sample; producing a set of moiety-bound nucleic acid particles upon incubation of the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the et of affinity moiety-coated microparticles; occluding a fluidic pathway of a cartridge upon displacement of a first subset of pin at the cartridge comprising the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles, within the fluidic pathway of the cartridge; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution. • U.S. Patent No. 9,540,636 at col. 9:34-42 (“In a specific example of this variation, releasing the nucleic acid sample comprises providing an elution solution that is in the range of pH 12-pH 13 to effect efficient elution/release of the bound target nucleic acid(s) from the microparticle based upon a shift to a more basic pH. In the specific example, the elution solution comprises 20 mM of NaOH; however, in other variations the elution solution can comprise any other suitable concentration of NaOH or KOH, depending upon the application (e.g., sample type).”) • U.S. Patent No. 9,540,636 at col. 9:56-67 (“Preferably, an elevated temperature in combination with an elevated pH resulting from the elution solution provides the enhanced conditions to facilitate the release of the nucleic acid sample. Furthermore, an elevated temperature (e.g., elevating a sample eluted at room temperature to 85 C) can function to minimize protease enzyme activity in the eluted nucleic acid and thereby improve the robustness of the detection of the target nucleic acid sample during processing in variations of Step S170; however, the method 100 can

Claim	Claim Language	Infringement Evidence
		<p>alternatively omit Step S161 in applications wherein heating the moiety-bound nucleic acid Volume is undesirable and/or unnecessary.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 10:3-14 (“In an example of Step S161, heating comprises elevating the temperature of the moiety-bound nucleic acid volume to 80-85 C, for 3 minutes, and in another example, heating comprises elevating the temperature of the moiety-bound nucleic acid volume to 50-70 C, for 3-10 minutes. In other examples, the elevation temperature can be maintained at a desired set point for as low as 1 minute or as high as 30 minutes. Further, elution conditions may be optimized to ensure that the bound nucleic acid is only eluted in the presence of the high pH solution at the elevated temperature for a specified amount of time.”) • U.S. Patent No. 9,540,636 at col. 14:22-28 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 500 uL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 30:60-61 (“ELUTION SOLUTION ELU-2 40 mM NaOH: ultrapure water (960 mL) and 1N NaOH (40 mL).”) • U.S. Patent No. 9,540,636 at col. 14:57-63 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 250 uL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 15:31-36 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL or 250 uL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 15:67-16:6 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 16:57-64 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-1 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 30:58-59 (“ELUTION SOLUTION ELU-1 20 mM NaOH: ultrapure water (980 mL) and 1N NaOH (20 mL).”)

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 17:29-34 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 17:66-18: (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the magnetic microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 18:37-43 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 19:13-19 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 19:51-57 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed twice with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 20:37-43 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 21:9-16 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160. DNA was eluted into 10 uL of ELU-2 and 2 uL of the eluate was used for real-time PCR in an example of Step S110.”) • U.S. Patent No. 9,540,636 at col. 21:42-48 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to

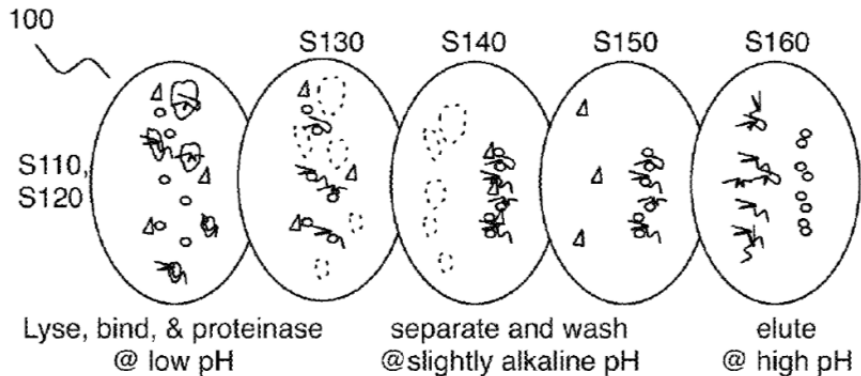
Claim	Claim Language	Infringement Evidence
		<p>85 C for 3 minutes in an example of Step S160.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,540,636 at col. 22:5-11 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) U.S. Patent No. 9,540,636 at col. 22:67-23: (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) U.S. Patent No. 9,540,636 at col. 23:42-48 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 or ELU-3 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) U.S. Patent No. 9,540,636 at col. 30:62-63 (“ELUTION SOLUTION ELU-3 40 mM KOH: ultrapure water (960 mL) and 1N KOH (40 mL).”) U.S. Patent No. 9,540,636 at col. 24:23-29 (“Upon removal of the unbound Supernatant in an example of Step S140, the PAA affinity moieties coated onto magnetic microparticles were washed twice (2x) with 500 uL of WSH-1 solution in an example of Step S150, and then the captured RNA and DNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”) <p>US10010888 (Exhibit 55)</p> <ul style="list-style-type: none"> Claim 17. The method of claim 14, further comprising delivering a release solution into the fluidic pathway, thereby producing a nucleic acid volume from the nucleic acid-magnetic bead sample. U.S. Patent No. 10,010,888 at col. 11:7-10 (“The cartridge heater 153 functions to transfer heat to a heating region 224 of a microfluidic cartridge 210, for inducing a pH shift to release bound nucleic acids from magnetic beads within the heating region 224.”) U.S. Patent No. 10,010,888 at col. 34:4-11 (“In embodiments wherein multiple heaters are provided, each heater is preferably independent to allow independent control of heating time and temperature for each sample. Step S442 functions to provide a heater, which, in combination with a release solution that provides a pH shift, facilitates a rapid and efficient unbinding of the nucleic acids from the magnetic beads.”)
1(h)	wherein the second set of	The accused workflow comprises releasing the polynucleotide from the plurality of binding particles under a second set of

Claim	Claim Language	Infringement Evidence																
	conditions includes increasing the pH to a second pH by addition of a hydroxide solution and increasing the temperature to a second temperature,	<p>conditions, wherein the second set of conditions includes increasing the pH to a second pH by addition of a hydroxide solution and increasing the temperature to a second temperature.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMoDx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none">• “A high pH NeuMoDx release reagent is dispensed into the S channel to cover the beads and heat is applied to complete the denaturation process, resulting in released nucleic acid or eluent.” 2:55-3:10 <p>40600114_Rev-C-SDS-NeuMoDx-Release-Solution-FINAL.pdf (Exhibit 78)</p> <table><tr><th colspan="4">Hazardous chemical ingredients per U.S. OSHA criteria (29 CFR 1910.1200 Hazard Communication):</th></tr><tr><th>Chemical Name</th><th>Identifiers</th><th>Classification</th><th>Concentration Percentages are by weight</th></tr><tr><td>Sodium Hydroxide (NaOH)</td><td>CAS-No. 1310-73-2 EC-No. 215-185-5 Index-No. 011-002-00-6 Registration No. 01-2119457892-27-XXXX</td><td>Metal Corrosive 1; Skin Corrosive 1B; Eye Damage 1; Aquatic Acute 3; H290, H314, H318, H402.</td><td><1% (</td></tr><tr><td>Deionized water</td><td>CAS-No. 7732-18-5</td><td>N/A</td><td>>99%</td></tr></table> <p>Odor: Odorless pH Value at 20°C (68°F) 11.8-12.8</p> <p>US9339812 (Exhibit 26)</p> <ul style="list-style-type: none">• Claim 7. The method of claim 6, wherein separating the volume of nucleic acids from the biological sample further comprises dispensing a release solution through the fluidic pathway by the fluid port.• Claim 8. The method of claim 7, wherein separating the volume of nucleic acids from the biological sample further comprises heating the first portion of the fluidic pathway to facilitate a pH shift, thus releasing nucleic acids from magnetic beads to produce the volume of nucleic acids.	Hazardous chemical ingredients per U.S. OSHA criteria (29 CFR 1910.1200 Hazard Communication):				Chemical Name	Identifiers	Classification	Concentration Percentages are by weight	Sodium Hydroxide (NaOH)	CAS-No. 1310-73-2 EC-No. 215-185-5 Index-No. 011-002-00-6 Registration No. 01-2119457892-27-XXXX	Metal Corrosive 1; Skin Corrosive 1B; Eye Damage 1; Aquatic Acute 3; H290, H314, H318, H402.	<1% (Deionized water	CAS-No. 7732-18-5	N/A	>99%
Hazardous chemical ingredients per U.S. OSHA criteria (29 CFR 1910.1200 Hazard Communication):																		
Chemical Name	Identifiers	Classification	Concentration Percentages are by weight															
Sodium Hydroxide (NaOH)	CAS-No. 1310-73-2 EC-No. 215-185-5 Index-No. 011-002-00-6 Registration No. 01-2119457892-27-XXXX	Metal Corrosive 1; Skin Corrosive 1B; Eye Damage 1; Aquatic Acute 3; H290, H314, H318, H402.	<1% (
Deionized water	CAS-No. 7732-18-5	N/A	>99%															

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> Claim 20. The method of claim 19, wherein producing the set of nucleic acid volumes from the set of nucleic acid-magnetic bead samples comprises: upon passing a magnet through one of the set of slots of the cartridge platform of the molecular diagnostic module, providing a magnetic field spanning a portion of each fluidic pathway in the set of fluidic pathways, thus capturing the set of nucleic acid-magnetic bead samples; dispensing a wash solution into each fluidic pathway of the set of fluidic pathways; dispensing a release solution into each fluidic pathway of the set of fluidic pathways; and heating each fluidic pathway of the set of fluidic pathways to facilitate a pH shift, thus unbinding nucleic acids from magnetic beads to produce the set of nucleic acid volumes. U.S. Patent No. 9,339,812 at col. 10:49-52 (“The cartridge heater functions to transfer heat to a heating region of a microfluidic cartridge, for inducing a pH shift to release bound nucleic acids from magnetic beads within the heating region.”) U.S. Patent No. 9,339,812 at col. 29:50-53 (“Step S442 functions to provide a heater, which, in combination with a release solution that provides a pH shift, facilitate a rapid and efficient unbinding of the nucleic acids from magnetic beads.”) <p>US9540636 (Exhibit 54)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,540,636 at col. 14:22-28 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 500 uL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) U.S. Patent No. 9,540,636 at col. 30:60-61 (“ELUTION SOLUTION ELU-2 40 mM NaOH: ultrapure water (960 mL) and 1N NaOH (40 mL).”) U.S. Patent No. 9,540,636 at col. 14:57-63 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 250 uL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) U.S. Patent No. 9,540,636 at col. 15:31-36 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL or 250 uL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”) U.S. Patent No. 9,540,636 at col.15:67-16:6 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an

Claim	Claim Language	Infringement Evidence
		<p>example of Step S160.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 16:57-64 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-1 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 30:58-59 (“ELUTION SOLUTION ELU-1 20 mM NaOH: ultrapure water (980 mL) and 1N NaOH (20 mL).”) • U.S. Patent No. 9,540,636 at col. 17:29-34 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 17:66-18: (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the magnetic microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 18:37-43 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 19:13-19 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 19:51-57 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed twice with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 20:37-43 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 21:9-16 (“Upon removal of the unbound Supernatant in an example of Step S140, the

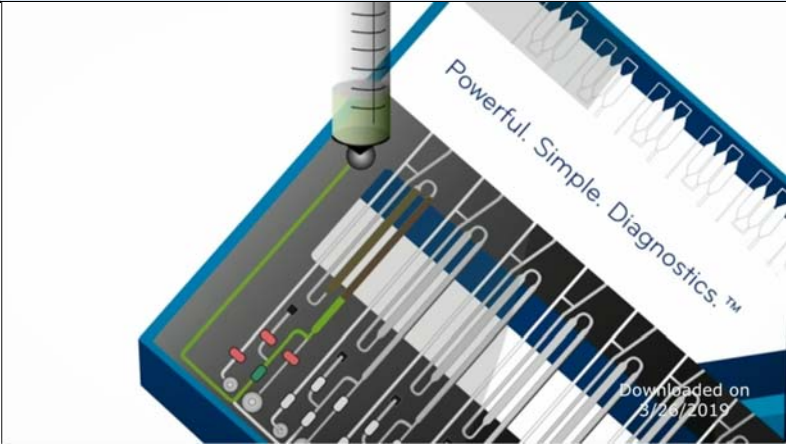
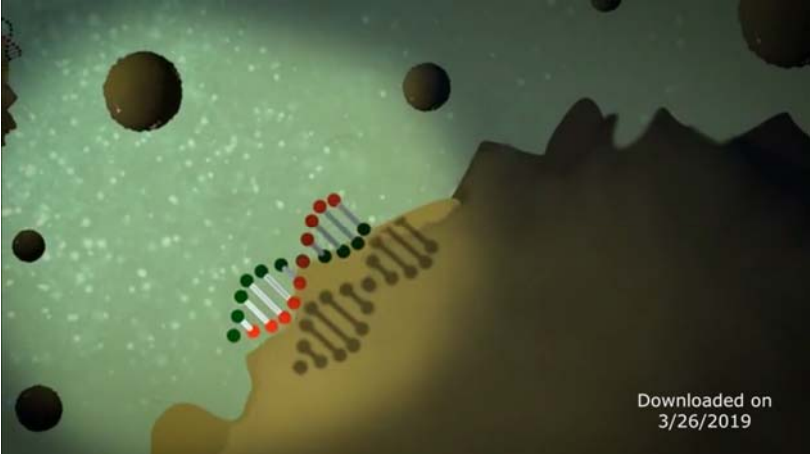
Claim	Claim Language	Infringement Evidence
		<p>magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160. DNA was eluted into 10 uL of ELU-2 and 2 uL of the eluate was used for real-time PCR in an example of Step S110.”)</p> <ul style="list-style-type: none">• U.S. Patent No. 9,540,636 at col. 21:42-48 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”)• U.S. Patent No. 9,540,636 at col. 22:5-11 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”)• U.S. Patent No. 9,540,636 at col. 22:67-23:6 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”)• U.S. Patent No. 9,540,636 at col. 23:42-48 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 or ELU-3 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”)• U.S. Patent No. 9,540,636 at col. 30:62-63 (“ELUTION SOLUTION ELU-3 40 mM KOH: ultrapure water (960 mL) and 1N KOH (40 mL).”)• U.S. Patent No. 9,540,636 at col. 24:23-29 (“Upon removal of the unbound Supernatant in an example of Step S140, the PAA affinity moieties coated onto magnetic microparticles were washed twice (2x) with 500 uL of WSH-1 solution in an example of Step S150, and then the captured RNA and DNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”) <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none">• Claim 15. The method of claim 1, wherein releasing the nucleic acid sample from the set of moiety-bound nucleic acid particles comprises contacting the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH that is in the range of pH 10 to pH 13.• Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and

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		<p>RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the microfluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20 uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction.</p>  <p style="text-align: center;">FIGURE 1C</p> <ul style="list-style-type: none">U.S. Patent No. 9,382,532 at col. 9:9-24 (“In one variation of Step S160, the affinity moieties, examples of which are described in Section 2 below, function based upon the pH of the environment. Specifically, at low pH, the affinity moieties are positively charged, which results in attraction to negatively charged nucleic acids; however, at high pH, the affinity moieties are negatively charged, which results in repulsion of negatively charged nucleic acids. In a

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		<p>specific example of this variation, releasing the nucleic acid sample comprises providing an elution solution that is in the range of pH 12-pH 13 to effect efficient elution/release of the bound target nucleic acid(s) from the microparticle based upon a shift to a more basic pH. In the specific example, the elution solution comprises 20 mM of NaOH: however, in other variations the elution Solution can comprise any other suitable concentration of NaOH or KOH, depending upon the application (e.g., sample type).”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at col. 9:38-49 (“Preferably, an elevated temperature in combination with an elevated pH resulting from the elution Solution provides the enhanced conditions to facilitate the release of the nucleic acid sample. Furthermore, an elevated temperature (e.g., elevating a sample eluted at room temperature to 85 C) can function to minimize protease enzyme activity in the eluted nucleic acid and thereby improve the robustness of the detection of the target nucleic acid sample during processing in variations of Step S110; however, the method 100 can alternatively omit Step S161 in applications wherein heating the moiety-bound nucleic acid Volume is undesirable and/or unnecessary.”) • U.S. Patent No. 9,382,532 at col. 14:54-61 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL or 250 uL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160. RNA was eluted into 10 uL of ELU-2 and 8 uL of the eluate was used for real-time RT-PCR in an example of Step 170.”) • U.S. Patent No. 9,382,532 at col. 28:64-65 (“Elution Solution ELU-2 - 40 mM NaOH: ultrapure water (960 mL) and 1N NaOH (40 mL).”) • U.S. Patent No. 9,382,532 at 15:19-26 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160. RNA was eluted into 10 uL of ELU-2 and 2 LL of the eluate was used for real-time RT-PCR in an example of Step S170.”) • U.S. Patent No. 9,382,532 at 16:2-14 (“DNA was allowed to bind to the DABAM affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature or 60 C depending on matrix used in examples of Step S130. Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-1 and heating the microparticles to 85 C for 3 minutes in an example of Step S160. DNA was eluted into 10 uL of ELU-1 and 8 ul of the eluate was used for real-time PCR in an example of Step S170.”) • U.S. Patent No. 9,382,532 at 28:62-63 (“Elution Solution ELU-1 - 20 mM NaOH: ultrapure water (980 mL) and 1N

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		<p>NaOH (20 mL).</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at 16:38-44 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500LL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at 17:4-10 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the magnetic microparticles to 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at 17:37-43 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at col. 18:8-16 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160. DNA was eluted into 10 uL of ELU-2 and 2 ul of the eluate was used for real-time PCR in an example of Step S170.”) • U.S. Patent No. 9,382,532 at col. 18:41-47 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed twice with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at 19:22-27 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at 19:56-61 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500LL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at 20:17-23 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150,

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		<p>and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”)</p> <ul style="list-style-type: none">• U.S. Patent No. 9,382,532 at col. 21:34-39 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500LL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85C for 3 minutes in an example of Step S160.”)• U.S. Patent No. 9,382,532 at col. 22:2-8 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 or ELU-3 and heating the microparticles to 85C for 3 minutes in an example of Step S160.”)• U.S. Patent No. 9,382,532 at col. 28:66-67 (“Elution Solution ELU-3–40 mM KOH: ultrapure water (960 mL) and 1N KOH (40 mL).”)
1(i)	wherein the second temperature is between 80° C and about 100° C	<p>The accused workflow comprises releasing the polynucleotide from the plurality of binding particles under a second set of conditions, wherein the second set of conditions includes increasing the pH to a second pH by addition of a hydroxide solution and increasing the temperature to a second temperature, wherein the second temperature is between 80° C and about 100° C.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none">• “A high pH NeuMoDx release reagent is dispensed into the S channel to cover the beads and heat is applied to complete the denaturation process, resulting in released nucleic acid or eluent.” 2:55-58• 2:58 Release reagent

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		<div><ul style="list-style-type: none">• 3:04 Heat/denaturation<p>40500098_D-IFU-NeuMoDx-Extraction-Plate-US-ONLY (Exhibit 59)</p><ul style="list-style-type: none">• “The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate lysis buffer in the NeuMoDx Extraction Plate and is subjected to lysis at pre-determined</div>

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		<p>temperatures in the presence of lytic enzymes and magnetic microspheres.” <i>Id.</i> at 1.</p> <p>40600100_Rev-D-IFU-NeuMoDx-WASH-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 58)</p> <ul style="list-style-type: none"> • The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. <p>40600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 20)</p> <ul style="list-style-type: none"> • The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. <p>40600103_Rev-D-IFU-NeuMoDx-Lysis-Buffer-4-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 66)</p> <ul style="list-style-type: none"> • The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of enriched Lim Broth is mixed with NeuMoDx Lysis Buffer 4 and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres dried in the NeuMoDx Extraction Plate. <p>On information and belief, the accused system comprises releasing the polynucleotide from the plurality of binding particles under a second set of conditions, wherein the second set of conditions includes increasing the pH to a second pH by addition of a hydroxide solution and increasing the temperature to a second temperature, wherein the second temperature is between 80° C and about 100° C.</p> <p>US9540636 (Exhibit 54)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col.14:22-28 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 500 uL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an

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		<p>example of Step S160.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 30:60-61 (“ELUTION SOLUTION ELU-2 40 mM NaOH: ultrapure water (960 mL) and 1N NaOH (40 mL).”) • U.S. Patent No. 9,540,636 at col. 14:57-63 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 250 uL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 15:31-36 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL or 250 uL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 15:67-16:6 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 16:57-64 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-1 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 30:58-59 (“ELUTION SOLUTION ELU-1 20 mM NaOH: ultrapure water (980 mL) and 1N NaOH (20 mL).”) • U.S. Patent No. 9,540,636 at col. 17:29-34 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 17:66-18:6 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the magnetic microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 18:37-43 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to

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		<p>85 C for 3 minutes in an example of Step S160.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 19:13-19 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 19:51-57 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed twice with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 20:37-43 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 21:9-16 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160. DNA was eluted into 10 uL of ELU-2 and 2 uL of the eluate was used for real-time PCR in an example of Step S110.”) • U.S. Patent No. 9,540,636 at col. 21:42-48 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 22:5-11 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 22:67-23: (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 23:42-48 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step

Claim	Claim Language	Infringement Evidence
		<p>S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 or ELU-3 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,540,636 at col. 30:62-63 (“ELUTION SOLUTION ELU-3 40 mM KOH: ultrapure water (960 mL) and 1N KOH (40 mL).”) U.S. Patent No. 9,540,636 at col. 24:23-29 (“Upon removal of the unbound Supernatant in an example of Step S140, the PAA affinity moieties coated onto magnetic microparticles were washed twice (2x) with 500 uL of WSH-1 solution in an example of Step S150, and then the captured RNA and DNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”) <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,382,532 at col. 14:54-61 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL or 250 uL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160. RNA was eluted into 10 uL of ELU-2 and 8 uL of the eluate was used for real-time RT-PCR in an example of Step 170.”) U.S. Patent No. 9,382,532 at col. 28:64-65 (“Elution Solution ELU-2 - 40 mM NaOH: ultrapure water (960 mL) and 1N NaOH (40 mL).”) U.S. Patent No. 9,382,532 at 15:19-26 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160. RNA was eluted into 10 uL of ELU-2 and 2 LL of the eluate was used for real-time RT-PCR in an example of Step S170.”) U.S. Patent No. 9,382,532 at 16:2-14 (“DNA was allowed to bind to the DABAM affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature or 60 C depending on matrix used in examples of Step S130. Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-1 and heating the microparticles to 85 C for 3 minutes in an example of Step S160. DNA was eluted into 10 uL of ELU-1 and 8 of the eluate was used for real-time PCR in an example of Step S170.”) U.S. Patent No. 9,382,532 at 28:62-63 (“Elution Solution ELU-1 - 20 mM NaOH: ultrapure water (980 mL) and 1N NaOH (20 mL).”) U.S. Patent No. 9,382,532 at 16:38-44 (“Upon removal of the unbound Supernatant in an example of Step S140, the


Claim	Claim Language	Infringement Evidence
		<p>magnetic microparticles with bound DNA were washed with 500LL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85C for 3 minutes in an example of Step S160.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at 17:4-10 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the magnetic microparticles to 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at 17:37-43 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at col. 18:8-16 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160. DNA was eluted into 10 uL of ELU-2 and 2 ul of the eluate was used for real-time PCR in an example of Step S170.”) • U.S. Patent No. 9,382,532 at col. 18:41-47 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed twice with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at 19:22-27 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at 19:56-61 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500LL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at 20:17-23 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”)

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none">• U.S. Patent No. 9,382,532 at col. 21:34-39 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500LL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85C for 3 minutes in an example of Step S160.”)• U.S. Patent No. 9,382,532 at col. 22:2-8 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 or ELU-3 and heating the microparticles to 85C for 3 minutes in an example of Step S160.”)• U.S. Patent No. 9,382,532 at col. 28:66-67 (“Elution Solution ELU-3–40 mM KOH: ultrapure water (960 mL) and 1N KOH (40 mL).”)

EXHIBIT 88

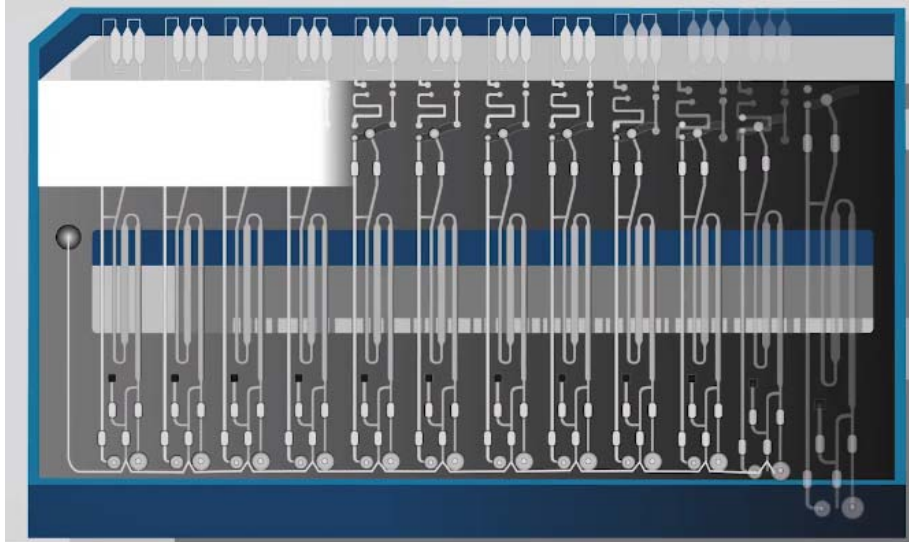
Exhibit 88

U.S. Patent No. 10,604,788 Infringement Chart

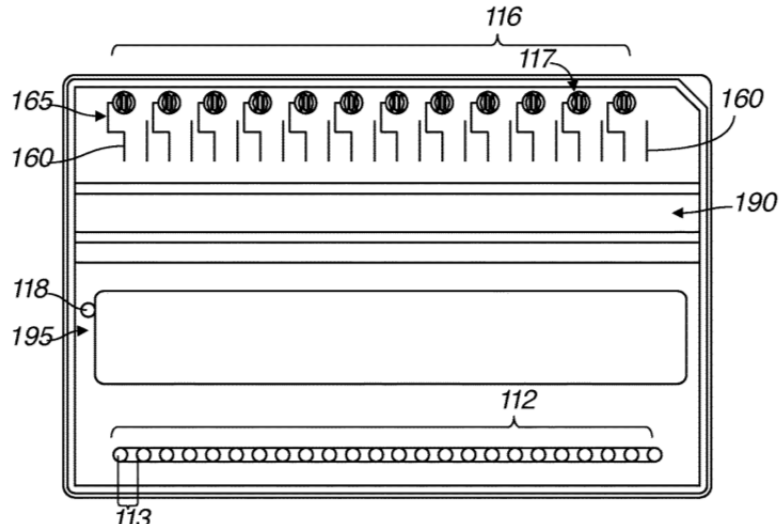
Claim	Claim Language	Infringement Evidence
1(a)	A system for processing polynucleotides in a biological sample, the system comprising	<p>To the extent that the preamble is limiting, the accused system comprises a system for processing polynucleotides in a biological sample.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-products/, last visited June 5, 2019 (Exhibit 12)</p> 

Claim	Claim Language	Infringement Evidence
		<p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul style="list-style-type: none"> • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result.” <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> • “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieving [sic] optimal operational and clinical performance for our customers and their patients.” • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents. • “The NeuMoDx™ 96 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 288 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 288 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/dr-steven-young-video-testimonial/, hyperlink at https://youtu.be/vukP6gbLBYE. (Exhibit 32)</p>

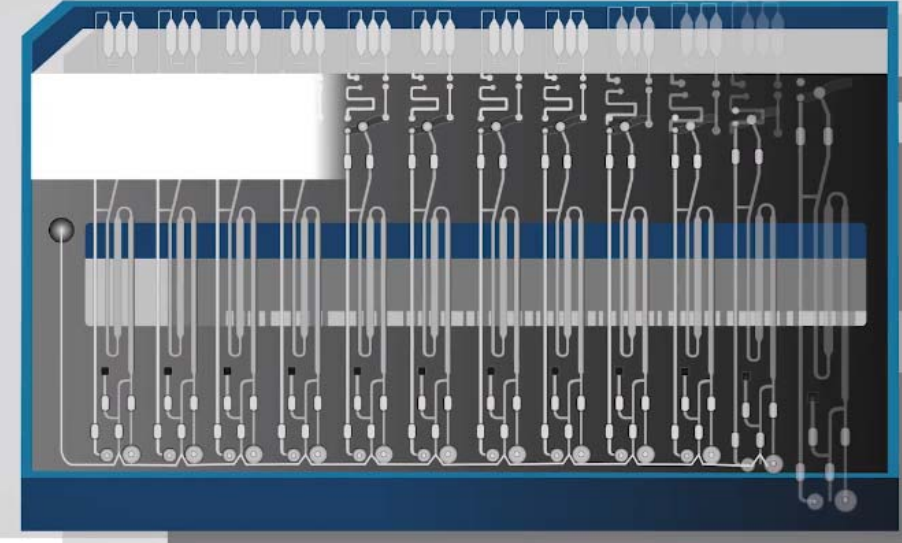
Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> At 2:58-3:18 (“There’s two systems that have been put into operation by NeuMoDx. One is the 288. It’s a high-throughput instrument, versus the 96, which is a lower throughput instrument. The advantage is that both systems use all of the same chemistry and all of the same hardware. It’s just a smaller footprint.”) <p><i>NeuMoDx™ Molecular Systems</i>, NeuMoDx, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul style="list-style-type: none"> “NeuMoDx™ Molecular Systems provide the industry’s first true continuous random-access solution and is scalable to meet the needs of the modern clinical laboratory. The ability to load samples and testing consumables on the fly offers up to 8 hours of operator walkaway capability. Room temperature stable reagents and consumables dramatically reduce waste resulting in unmatched flexibility. Liquid handling and transport is achieved through proven robotic technologies. Our proprietary and unitized microfluidic cartridge features independent lanes allowing for simultaneous processing of sample types and varying assays.” <p><i>NeuMoDx™ Molecular Systems</i>, NeuMoDx, http://www.neumodx.com/, last visited April 9, 2020 (Exhibit 48)</p> <ul style="list-style-type: none"> “NeuMoDx™ Molecular Systems provide the industry’s first true continuous random-access solution and is scalable to meet the needs of the modern clinical laboratory. The ability to load samples and testing consumables on the fly offers up to 8 hours of operator walkaway capability. Room temperature stable reagents and consumables dramatically reduce waste resulting in unmatched flexibility. Liquid handling and transport is achieved through proven robotic technologies. Our proprietary and unitized microfluidic cartridge features autonomous lanes allowing for simultaneous processing of sample types and varying assays.”
1(b)	a microfluidic device comprising substrate layers that define a microfluidic network,	<p>The accused system comprises a microfluidic device comprising substrate layers that define a microfluidic network.</p> <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System... The NeuMoDx

Claim	Claim Language	Infringement Evidence
		<p>Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.”</p> <p>K173725.pdf (Exhibit 23)</p> <ul style="list-style-type: none"> “510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY ASSAY AND INSTRUMENT COMBINATION TEMPLATE... Test Principle... After reconstitution of the dried PCR reagents, the NeuMoDx System dispenses the prepared PCR-ready mixture into one PCR chamber (per specimen) of the NeuMoDx Cartridge. Amplification and detection of the control and target DNA sequences occur in PCR chamber.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59 

Claim	Claim Language	Infringement Evidence										
		<p>On information and belief, the accused system comprises a microfluidic device comprising substrate layers that define a microfluidic network.</p> <p>“Patents”, http://www.neumodx.com/patents/, (Exhibit 47) demonstrating that NeuMoDx marks its products with US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; 9,452,430; 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; 10,010,888; 9,382,532; 9,540,636; 9,499,896; 10,239,060; 9,539,576; 10,226,771, 9,637,775; and 10,093,963</p> <h2>PATENTS</h2> <table><tr><th>Product</th><th>Patents</th></tr><tr><td>CARTRIDGE</td><td>US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.</td></tr><tr><td>P02 (overall system and method)</td><td>US Patent Nos. 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; and 10,010,888. CN Patent No. 201380009286.3.</td></tr><tr><td>EXTRACTION PLATE</td><td>US Patent Nos. 9,382,532; and 9,540,636. DE Patent No. 60 2013 056 932.0. DK Patent No. 2912174. EP Patent No. EP-B-2912174. ES Patent No. 300330453. FR Patent No. 2912174. GB Patent No. 2912174. IT Patent No. 502019000064944. NO Patent No. 2912174. SE Patent No. 2912174.</td></tr><tr><td>XPCR MODULE</td><td>US Patent Nos. 9,499,896; 10,239,060; 9,539,576; 10,226,771; 9,637,775; 10,093,963; 9,604,213; and 10,010,888.</td></tr></table> <p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none">Claim 1. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer, defining a sample port, a reagent port, a fluid port, and a detection chamber; an elastomeric layer; an intermediate substrate coupled to the first layer, such that the elastomeric layer is situated between the intermediate substrate and the first layer, wherein the intermediate substrate defines a chamber with a corrugated surface directly	Product	Patents	CARTRIDGE	US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.	P02 (overall system and method)	US Patent Nos. 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; and 10,010,888. CN Patent No. 201380009286.3.	EXTRACTION PLATE	US Patent Nos. 9,382,532; and 9,540,636. DE Patent No. 60 2013 056 932.0. DK Patent No. 2912174. EP Patent No. EP-B-2912174. ES Patent No. 300330453. FR Patent No. 2912174. GB Patent No. 2912174. IT Patent No. 502019000064944. NO Patent No. 2912174. SE Patent No. 2912174.	XPCR MODULE	US Patent Nos. 9,499,896; 10,239,060; 9,539,576; 10,226,771; 9,637,775; 10,093,963; 9,604,213; and 10,010,888.
Product	Patents											
CARTRIDGE	US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.											
P02 (overall system and method)	US Patent Nos. 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; and 10,010,888. CN Patent No. 201380009286.3.											
EXTRACTION PLATE	US Patent Nos. 9,382,532; and 9,540,636. DE Patent No. 60 2013 056 932.0. DK Patent No. 2912174. EP Patent No. EP-B-2912174. ES Patent No. 300330453. FR Patent No. 2912174. GB Patent No. 2912174. IT Patent No. 502019000064944. NO Patent No. 2912174. SE Patent No. 2912174.											
XPCR MODULE	US Patent Nos. 9,499,896; 10,239,060; 9,539,576; 10,226,771; 9,637,775; 10,093,963; 9,604,213; and 10,010,888.											

Claim	Claim Language	Infringement Evidence
		<p>opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface includes a set of openings that provide access to the elastomeric layer; and a fluidic pathway, wherein the fluidic pathway is fluidically coupled to the sample port, the reagent port, the fluid port, and the detection chamber.</p> <ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at FIG. 1A:  <p style="text-align: center;">FIG. 1A</p> <ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at Abstract (“A microfluidic cartridge, configured to facilitate processing and detection of nucleic acids, comprising: a top layer comprising a set of cartridge-aligning indentations, a set of sample port-reagent port pairs, a shared fluid port, a vent region, a heating region, and a set of detection chambers; an intermediate substrate, coupled to the top layer comprising a waste chamber; an elastomeric layer, partially situated on the intermediate substrate; and a set of fluidic pathways, each formed by at least a portion of the top layer and a portion of the elastomeric layer, wherein each fluidic pathway is fluidically coupled to a sample port-reagent port pair, the shared fluid port, and a detection chamber, comprises a turnabout portion passing through the heating region, and is configured to be occluded upon deformation of the elastomeric layer, to transfer a waste fluid to the waste

Claim	Claim Language	Infringement Evidence
		<p>chamber, and to pass through the vent region.”)</p> <ul style="list-style-type: none"> US Patent No. 9,738,887 at 13:35-42. (“The set of fluidic pathways 160 of the microfluidic cartridge 100 functions to provide a fluid network into which volumes of sample fluids, reagents, buffers and/or gases used in a molecular diagnostics protocol may be delivered, out of which waste fluids may be eliminated, and by which processed nucleic acid samples may be delivered to a detection chamber for analysis, which may include amplification and/or detection.”) <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate.
1(c)	the microfluidic network comprising a first processing region;	<p>The accused system comprises the microfluidic network comprising a first processing region.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p>

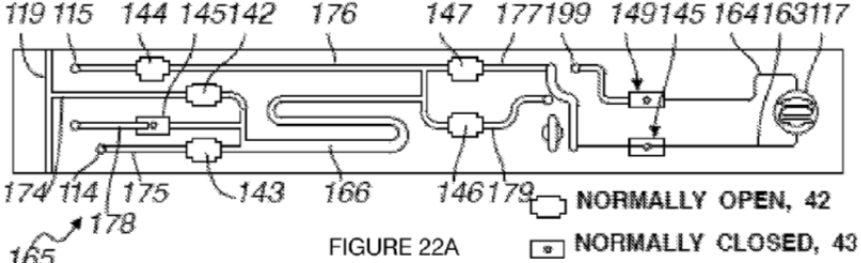
Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none"> • “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” <i>Id.</i> at 2:28-2:39. • <i>Id.</i> at 2:28 (showing lysate in the s-channel).

Claim	Claim Language	Infringement Evidence
		<div data-bbox="730 228 1692 773"> </div> <ul style="list-style-type: none"> • “A precise volume of air is then applied to remove any remaining liquid into the waste chamber. NeuMoDx wash solution is pumped via the fluid port into the microfluidic cartridge to remove all unbound material, followed by another volume of air to remove excess wash solution. High pH NeuMoDx release reagent is dispensed into the s-channel to cover the beads, and heat is applied to the denaturation process, resulting in released nucleic acid or eluate.” <i>Id.</i> at 2:39-3:12. • <i>Id.</i> at 2:43-3:00 (showing dispensing of the wash solution and release solution) <div data-bbox="682 1029 1740 1331"> </div> <p data-bbox="632 1370 1995 1403">40600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 20)</p>

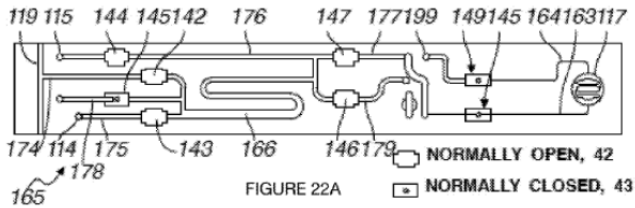
Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40500098_D-IFU-NeuMoDx-Extraction-Plate-US-ONLY (Exhibit 59)</p> <ul style="list-style-type: none"> “The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution.” <i>Id.</i> at 1. <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound nucleic acid is eluted using the NeuMoDx™ RELEASE Solution. <p>40600106_Rev-D-IFU-NeuMoDx-Lysis-Buffer-1-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 63)</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600105_Rev-D-IFU-NeuMoDx-Lysis-Buffer-2-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 64)</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE

Claim	Claim Language	Infringement Evidence
		<p>Solution.</p> <p>40600104_Rev-D-IFU-NeuMoDx-Lysis-Buffer-3-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 65)</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600103_Rev-D-IFU-NeuMoDx-Lysis-Buffer-4-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 66)</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 20)</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600100_-Rev-D-IFU-NeuMoDx-WASH-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 58)</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>US9382532 (Exhibit 52)</p>

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10. • Claim 6. The method of claim 5, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety-sample mixture from the process chamber; occluding the fluidic pathway of the cartridge-at a set of occlusion positions upon displacement of pins of the set of pins to generate a path through a magnetic field, and to a waste chamber; and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber. • Claim 10. The method of claim 3, wherein washing the set of moiety-bound nucleic acid particles comprises aspirating the moiety-sample mixture; receiving the cartridge at the cartridge receiving module comprising the set of pins and a cam card interfacing with the set of pins; transitioning the cartridge to an active configuration that disposes the cartridge proximal the set of pins; displacing the first subset of the set of pins in the active configuration of the cartridge, upon translation of the cam card relative to the set of pins, thereby occluding the fluidic pathway of

Claim	Claim Language	Infringement Evidence
		<p>the cartridge at a set of occlusion positions; delivering the moiety-sample mixture into the fluidic pathway, wherein the fluidic pathway is configured to pass through a magnetic field and is coupled to a waste chamber, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field; and delivering a wash solution through the fluidic pathway and into the waste chamber in a continuous flow operation.</p> <ul style="list-style-type: none"> Claim 13. The method of claim 3, wherein releasing the nucleic acid sample from the set of moiety-bound nucleic acid particles comprises occluding the fluidic pathway of the cartridge, comprising the process chamber, at a set of occlusion positions, upon displacement of pins of the set of pins, to define a path through a magnetic field; delivering the set of moiety-bound nucleic acid particles into the path of the fluidic pathway; and delivering an elution solution into the fluidic pathway, thereby inducing a pH shift configured to release the nucleic acid sample from the set of moiety-bound nucleic acid particles. U.S. Patent No. 9,382,532 at FIG. 22A:  <p>FIGURE 22A</p> <ul style="list-style-type: none"> U.S. Patent No. 9,382,532 at 25:35-50 (“A volume of release solution will still be maintained within the capture segment 166 at this stage. The first and the fourth occlusion positions 142, 145 may then be occluded to form a sixth truncated pathway sealing the volume of release solution, with the captured magnetic beads bound to nucleic acids, within the capture segment 166. ...Release solution may be sealed within capture segments of other fluidic pathways using a similar process. A heater may then be provided at the sixth truncated pathway, inducing a pH shift within the sixth truncated pathway to unbind nucleic acids from the magnetic beads.”) <p>US9441219 (Exhibit 53)</p>

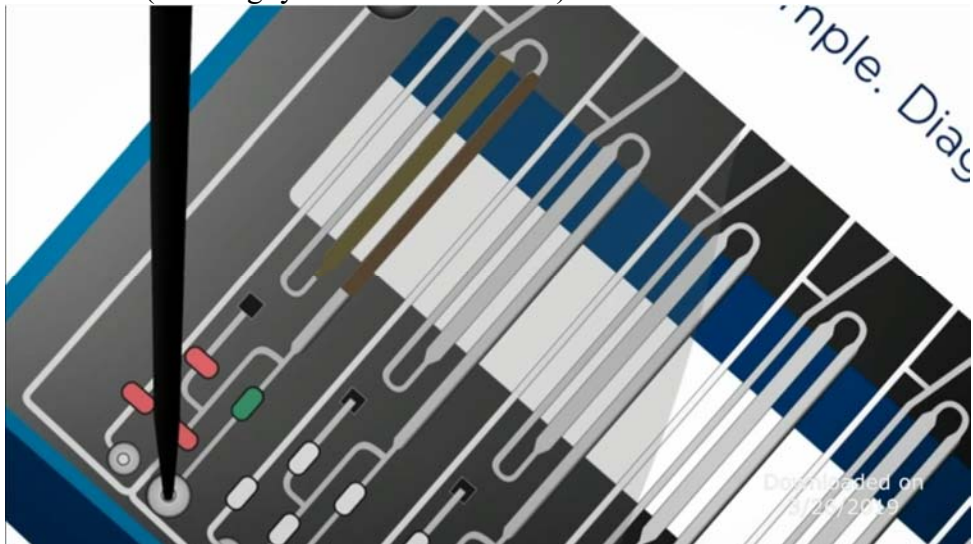
Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> Claim 14. The system of claim 8, further comprising a capture plate comprising a well containing a set of magnetic beads, a lysing reagent, and a sample process control, configured to be combined with the biological sample, wherein the capture plate facilitates production of a magnetic bead-sample from the biological sample and the set of magnetic beads; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the cartridge, and configured to transfer a nucleic acid volume processed from the magnetic bead-sample from the cartridge. U.S. Patent No. 9,441,219 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids. U.S. Patent No. 9,441,219 at col. 3:28-35 (“The liquid handling system 250 then aspirates substantially all of each sample of the set of lysed biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate no, and dispenses the set of magnetic bead-samples into a microfluidic cartridge 210, aligned within a cartridge receiving module 140 of a molecular diagnostic module 130, and configured to be manipulated by the molecular diagnostic module 130.”) U.S. Patent No. 9,441,219 at col. 29:30-35 (“Step S430 recites transferring each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways, and functions to isolate each of the set of nucleic acid-magnetic bead samples within separate pathways for further processing.”) <p>US9540636 (Exhibit 54)</p> <ul style="list-style-type: none"> Claim 5. The method of claim 4, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety sample mixture

Claim	Claim Language	Infringement Evidence
		<p>from the process chamber, occluding the fluidic pathway of the cartridge at a set of occlusion positions upon displacement of pins of the set of pins to generate a path through a magnetic field, and to a waste chamber, and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber.</p> <ul style="list-style-type: none"> Claim 7. The method of claim 3, wherein washing the set of moiety-bound nucleic acid particles comprises aspirating the moiety-sample mixture; receiving the cartridge at the cartridge receiving module comprising the set of pins and a cam card interfacing with the set of pins; transitioning the cartridge to an active configuration that disposes the cartridge to a position that is proximal to the set of pins; displacing the first subset of the set of pins in the active configuration of the cartridge, upon translation of the cam card relative to the set of pins, thereby occluding the fluidic pathway of the cartridge at a set of occlusion positions; delivering the moiety-sample mixture into the fluidic pathway, wherein the fluidic pathway is configured to pass through a magnetic field and is coupled to a waste chamber, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field; and delivering a wash solution through the fluidic pathway and into the waste chamber in a continuous flow operation.  <p>FIGURE 22A</p> <p>US10010888 (Exhibit 55)</p> <ul style="list-style-type: none"> Claim 8. The system of claim 6, wherein the capture segment is an s-shaped capture segment, and wherein in an operation mode of the system the magnet is configured to cross a portion of the capture segment in a direction perpendicular to a flow direction through the capture segment thereby providing a magnetic field at the portion of the capture segment. Claim 16. The method of claim 14, wherein transferring the nucleic acid-magnetic bead sample o the fluidic pathway of the cartridge comprises transferring the nucleic acid-

Claim	Claim Language	Infringement Evidence
		<p>magnetic bead sample into an s-shaped capture segment passing between the heating region and the magnet housing region of the cartridge.</p> <ul style="list-style-type: none"> U.S. Patent No. 10,010,888 at col. 33:12-17 (“Step S430 recites transferring each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways, and functions to isolate each of the set of nucleic acid-magnetic bead samples within separate pathways for further processing.”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 2. The system of claim 1, further comprising a liquid handling system configured to transfer at least one magnetic bead-sample from the capture plate to the molecular diagnostic module, and to aspirate at least one nucleic acid volume from the molecular diagnostic module. Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprising a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) U.S. Patent No. 9,050,594 at col. 3:33-41 (“The liquid handling system 250 then aspirates substantially all of each sample of the set of lysed biological samples combined with

Claim	Claim Language	Infringement Evidence
		<p>magnetic beads (i.e., set of magnetic bead-samples) from the capture plate no, and dispenses the set of magnetic bead-samples into a microfluidic cartridge 210, aligned within a cartridge receiving module 140 of a molecular diagnostic module 130, and configured to be manipulated by the molecular diagnostic module 130.”)</p> <p>US9452430 (Exhibit 56)</p> <ul style="list-style-type: none"> • Claim 9. The cartridge of claim 1, wherein the sealed waste chamber further defines a second external void parallel to the external void and configured to receive a magnet, wherein the second external void provides access to a magnetic capture segment of the fluidic pathway, wherein the magnetic capture segment is downstream of the sample port and upstream of the waste port. • Claim 10. The cartridge of claim 9, wherein the intermediate substrate includes a magnet proximal the second external void and the magnetic capture segment. • Claim 13. The cartridge of claim 12, wherein the first fluidic pathway comprises a capture segment, wherein the capture segment is s-shaped and progressively narrowing in an upstream-to-downstream direction • U.S. Patent No. 9,452,430 at col. 12:55-58 (“The magnet housing region 150 of the microfluidic cartridge 100 functions to provide access to and/or house at least one magnet 152 providing a magnetic field 156 for purification and isolation of nucleic acids.”) <p>US9604213 (Exhibit 30)</p> <ul style="list-style-type: none"> • Claim 1. A system for processing and detecting nucleic acids in cooperation with a cartridge comprising a heating region defined at a first surface, and a magnet housing region defined at a second surface in thermal communication with the first surface, the system comprising: a capture plate configured to facilitate combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate and separate nucleic acids from the set of magnetic beads, comprising: a cartridge platform configured to receive the cartridge and comprising a magnet receiving slot aligned with the second Surface during operation, a heater configured to transmit heat to the heating region at the first Surface during operation, and a magnet coupled to a magnet heating element that heats the magnet during operation with the magnet proximal the second Surface, the magnet configured to pass through the magnet receiving

Claim	Claim Language	Infringement Evidence
		<p>slot into the magnet housing region during operation, thereby facilitating separation of a nucleic acid Volume from the magnetic bead-sample and heating of the magnetic bead-sample in cooperation with the heater</p> <ul style="list-style-type: none"> • Claim 4. The system of claim 3, wherein the capture segment is an s-shaped capture segment, and wherein in an operation mode of the system the magnet is configured to cross a subset of the capture segment in a direction perpendicular to a flow direction through the capture segment thereby providing a magnetic field at the subset of the capture segment to capture the magnetic-bead sample within the capture segment. • Claim 14. The system of claim 1, wherein the molecular diagnostic module is configured to receive and align a microfluidic cartridge comprising a set of sample-port-reagent port pairs, a fluidic port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a capture segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • U.S. Patent No. 9,604,213 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling Subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation Subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical Subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay Strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) • U.S. Patent No. 9,604,213 at col. 3:28-35 (“The liquid handling system 250 then aspirates substantially all of each sample of the set of lysed biological samples combined with magnetic beads (i.e., set of magnetic bead samples) from the capture plate no, and dispenses the set of magnetic bead-samples into a microfluidic cartridge 210, aligned within a cartridge receiving module 140 of a molecular diagnostic module 130, and configured to be manipulated by the molecular diagnostic module 130.”)

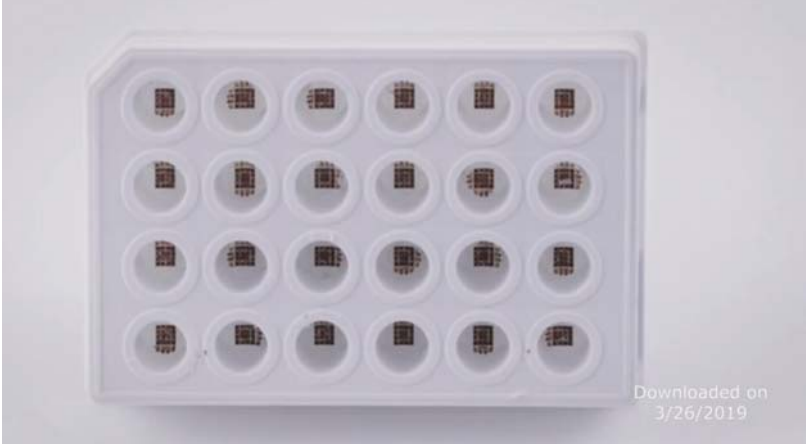

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> U.S. Patent No. 9,604,213 at 15:57-64 (“In any of the above embodiments and variations of the magnet(s), the magnet(s) are preferably configured to span a substantial portion of a capture segment 263 (e.g., an s-shaped capture segment with a characteristic width) of the microfluidic cartridge 210, by way of the magnet housing region 218, wherein the capture segment is a portion of a fluidic pathway configured to facilitate capture of target particles bound to magnetic particles.”)
1(d)	the microfluidic device further comprising a waste chamber downstream of the first processing region	<p>The accused system comprises a microfluidic device further comprising a waste chamber downstream of the first processing region.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” <i>Id.</i> at 2:28-2:39. <i>Id.</i> at 2:28 (showing lysate in the s-channel). 

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • “A precise volume of air is then applied to remove any remaining liquid into the waste chamber. NeuMoDx wash solution is pumped via the fluid port into the microfluidic cartridge to remove all unbound material, followed by another volume of air to remove excess wash solution. High pH NeuMoDx release reagent is dispensed into the s-channel to cover the beads, and heat is applied to the denaturation process, resulting in released nucleic acid or eluate.” <i>Id.</i> at 2:39-3:12. <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> • Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position of the fluidic pathway, by way of the void of the corrugated surface, the fluidic pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber. <p>US9101930 (Exhibit 25)</p> <ul style="list-style-type: none"> • Claim 10. A cartridge, configured to facilitate processing and detecting of nucleic acids, comprising: a first layer and an intermediate substrate, coupled to the first layer, wherein the intermediate substrate defines a waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids spanning a majority of a width of the intermediate substrate and external to the waste chamber, wherein the set of voids is accessible from a direction perpendicular to a broad surface of the first layer; a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway, formed by at least a portion of the first layer, wherein the first fluidic pathway and the second fluidic pathway are each superior to the intermediate substrate, are each at least partially separated from the corrugated surface of the intermediate substrate by an elastomeric layer and are each configured to transfer waste to the waste chamber through a set of openings of the intermediate substrate.

Claim	Claim Language	Infringement Evidence
		<p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprising a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. <p>US9452430 (Exhibit 56)</p> <ul style="list-style-type: none"> Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port; an intermediate substrate that is coupled to the first layer, partially separated from the first layer by a film layer, and configured to form a sealed waste chamber and a waste port into the sealed waste chamber, wherein the sealed waste chamber directly opposes the first layer across the film layer and defines an external void; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the sealed waste chamber by a deformable layer, wherein the fluidic pathway is fluidly coupled to the sample port, and wherein, upon deformation of the deformable layer through the external void defined by the waste chamber, the fluidic pathway is occluded and configured to transfer waste fluid of the sample through the waste port into an interior portion of the sealed waste chamber. Claim 11. The cartridge for processing of a set of samples, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate forms a sealed waste chamber and a set of waste ports into the sealed waste chamber, wherein the sealed waste chamber directly opposes the first layer across the film layer and defines an external void; a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the first layer, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the sealed wax chamber by a deformable layer that is deformed through the external void, and each of the first and second fluidic pathways is configured to transfer waste fluid of the set of samples into the sealed waste chamber through the set of waste ports.

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> Claim 12. The cartridge of claim 11, wherein the deformable layer includes a set of waste openings aligned with the set of waste ports, thereby allowing transfer of waste fluid from the set of samples into the sealed waste chamber. <p>US9540636 (Exhibit 54)</p> <ul style="list-style-type: none"> Claim 5. The method of claim 4, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety sample mixture from the process chamber, occluding the fluidic pathway of the cartridge at a set of occlusion positions upon displacement of pins of the set of pins to generate a path through a magnetic field, and to a waste chamber, and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber. <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> Claim 6. The method of claim 5, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety-sample mixture from the process chamber; occluding the fluidic pathway of the cartridge-at a set of occlusion positions upon displacement of pins of the set of pins to generate a path through a magnetic field, and to a waste chamber; and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber. U.S. Patent No. 9,382,532 at Abstract (“A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber; mixing the binding moiety solution with a biological sample, within the process chamber, in order to produce a moiety-sample mixture; incubating the moiety-sample mixture during a time window, thereby producing a solution comprising a set of moiety-bound nucleic acid particles and a waste volume; separating the set of moiety-bound nucleic acid particles from the waste volume; washing the set of moiety-bound nucleic acid particles; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles.”)
1(e)	a lysing container located external to the substrate layers,	<p>The accused system comprises a lysing container located external to the substrate layers.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936 (Exhibit 16)</p> <ul style="list-style-type: none"> “Liquid Handling Processing A: Lysis and Capture. Dispensing lysis buffer. Dispensing lysis buffer and patient specimen into extraction plate. The liquid handling robot delivers lysis buffer and patient specimen to the extraction plate, which has 24 independent wells which contain NeuDry affinity-coated paramagnetic beads. Each mixture is aspirated and dispensed five times to ensure homogeneity of the solution. During the transfer of patient specimen to the extraction plate the liquid handling robot uses pre-defined no-fly zones to reduce the potential of contamination.” <i>Id.</i> at 0:28-1:05

Claim	Claim Language	Infringement Evidence
		<div data-bbox="638 237 1438 678">  <p>Downloaded on 3/26/2019</p> </div> <ul style="list-style-type: none"> • “Each extraction plate well is then heated independently for 10 minutes to ensure proper lysing and binding of the nucleic acids to the paramagnetic beads. The temperatures applied range from 37 degrees Celsius to 60 degrees Celsius, resulting in the flexibility to process a wide variety of DNA and RNA IVD and LDT tests simultaneously.” <i>Id.</i> at 1:05-1:35 • <i>Id.</i> at 1:16 (showing binding of nucleic acids to paramagnetic beads). <div data-bbox="732 868 1644 1382">  <p>Downloaded on 3/26/2019</p> </div> <ul style="list-style-type: none"> • “After thoroughly mixing the solution in each well of the extraction plate, the crude lysate is

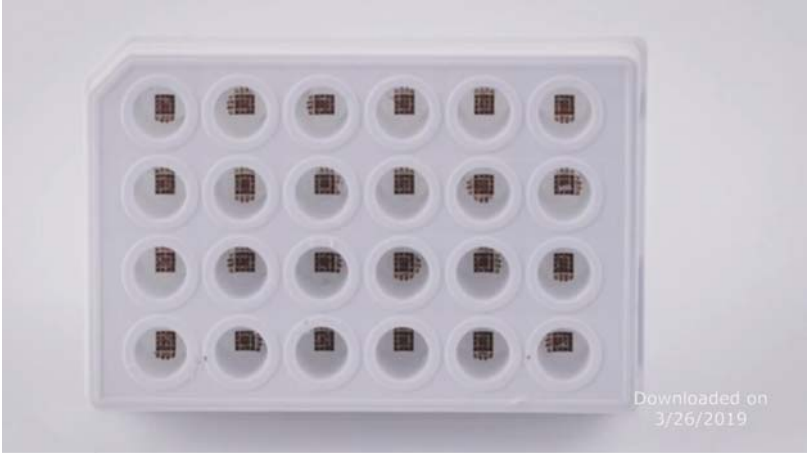
Claim	Claim Language	Infringement Evidence
		<p>independently aspirated from each well and transferred to the NeuMoDx cartridge.” <i>Id.</i> at 1:35-1:51.</p> <p>40600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 20)</p> <ul style="list-style-type: none"> • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40500098_D-IFU-NeuMoDx-Extraction-Plate-US-ONLY (Exhibit 59)</p> <ul style="list-style-type: none"> • “The NeuMoDx™ Extraction Plate contains a proprietary, dried reagent used for the efficient extraction of nucleic acids on the NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems (NeuMoDx™ System(s)) in conjunction with other NeuMoDx™ reagents such as NeuMoDx™ lysis buffers, NeuMoDx™ WASH Solution and the NeuMoDx™ RELEASE Solution. The NeuMoDx™ Extraction Plate is universally used for all tests processed on the NeuMoDx Systems and is formulated to perform both RNA and DNA extraction.” <i>Id.</i> at 1. • “Each 24-well NeuMoDx Extraction Plate contains dried, room-temperature stable reagents including proprietary coated magnetic microspheres, a lytic enzyme, and RNA and DNA Sample Process Controls. Components within the extraction plate work in conjunction with the appropriate NeuMoDx lysis buffer to lyse cells in a temperature dependent manner and bind the nucleic acid while reducing activity of any nucleases present in clinical samples. The Sample Process Controls bind to the magnetic microspheres at the same time as the target nucleic acid, and are carried throughout the extraction procedure, serving as internal controls to monitor for any inefficiencies in the extraction process and presence of PCR interference substances.” <i>Id.</i> at 1. • “The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate lysis buffer in the NeuMoDx Extraction Plate and is subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres.” <i>Id.</i> at 1.

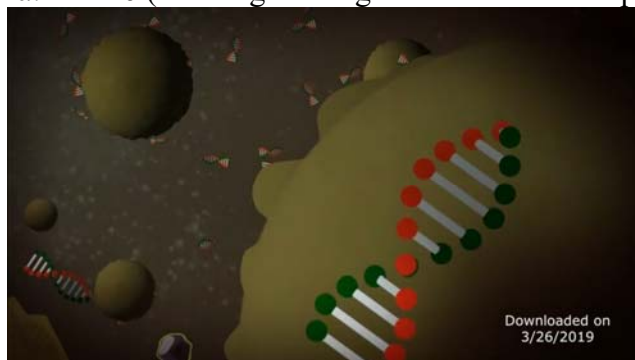
Claim	Claim Language	Infringement Evidence																								
		<div><ul style="list-style-type: none">“The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution.” <i>Id.</i> at 1.</div> <div><p><i>Material Provided</i></p><table><tr><th>REF</th><th>Contents</th><th>Tests per unit</th><th>Tests per carton</th></tr><tr><td>100200</td><td>NeuMoDx™ Extraction Plate <i>Dried magnetic affinity microspheres, lytic enzymes, and sample process controls</i></td><td>24</td><td>384</td></tr></table></div> <div><p><i>NeuMoDx™ Reagents and Consumables Required But Not Provided</i></p><table><tr><th>REF</th><th>Contents</th></tr><tr><td>400400, 400500 400600, 400700</td><td>NeuMoDx™ Lysis Buffer 1, 2, 3 and/or 4</td></tr><tr><td>400100</td><td>NeuMoDx™ WASH Solution</td></tr><tr><td>400200</td><td>NeuMoDx™ RELEASE Solution</td></tr><tr><td>100100</td><td>NeuMoDx™ Cartridge</td></tr><tr><td><i>various</i></td><td>NeuMoDx™ test strip (<i>as applicable</i>)</td></tr><tr><td>235903</td><td>Hamilton CO-RE Tips (300 µL) with Filters (available from NeuMoDx or Hamilton)</td></tr><tr><td>235905</td><td>Hamilton CO-RE Tips (1000 µL) with Filters (available from NeuMoDx or Hamilton)</td></tr></table></div> <div><p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p><ul style="list-style-type: none">The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx™ lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres.The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx Cartridge where the unbound/non-specifically bound components are washed away using the</div>	REF	Contents	Tests per unit	Tests per carton	100200	NeuMoDx™ Extraction Plate <i>Dried magnetic affinity microspheres, lytic enzymes, and sample process controls</i>	24	384	REF	Contents	400400, 400500 400600, 400700	NeuMoDx™ Lysis Buffer 1, 2, 3 and/or 4	400100	NeuMoDx™ WASH Solution	400200	NeuMoDx™ RELEASE Solution	100100	NeuMoDx™ Cartridge	<i>various</i>	NeuMoDx™ test strip (<i>as applicable</i>)	235903	Hamilton CO-RE Tips (300 µL) with Filters (available from NeuMoDx or Hamilton)	235905	Hamilton CO-RE Tips (1000 µL) with Filters (available from NeuMoDx or Hamilton)
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Claim	Claim Language	Infringement Evidence																								
		<p>NeuMoDx™ WASH Solution and the bound nucleic acid is eluted using the NeuMoDx™ RELEASE Solution.</p> <p><i>Material Provided</i></p> <table><tr><th>REF</th><th>Contents</th><th>Tests per unit</th><th>Tests per carton</th></tr><tr><td>100100</td><td>NeuMoDx™ Cartridge</td><td>12</td><td>576</td></tr></table> <p><i>NeuMoDx™ Reagents and Consumables Required But Not Provided</i></p> <table><tr><th>REF</th><th>Contents</th></tr><tr><td>400400, 400500 400600, 400700</td><td>NeuMoDx™ Lysis Buffer 1, 2, 3 and/or 4</td></tr><tr><td>100200</td><td>NeuMoDx™ Extraction Plate <i>Dried magnetic affinity microspheres, lytic enzymes, and sample process controls</i></td></tr><tr><td>400100</td><td>NeuMoDx™ WASH Solution</td></tr><tr><td>400200</td><td>NeuMoDx™ RELEASE Solution</td></tr><tr><td>various</td><td>NeuMoDx™ test strip <i>(as applicable)</i></td></tr><tr><td>235903</td><td>Hamilton CO-RE Tips (300 µL) with Filters (available from NeuMoDx or Hamilton)</td></tr><tr><td>235905</td><td>Hamilton CO-RE Tips (1000 µL) with Filters (available from NeuMoDx or Hamilton)</td></tr></table> <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none">• Claim 24. The system of claim 23, further comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample, a lysing reagent, and a sample process control, wherein the capture plate facilitates production of at least one biological sample combined with magnetic beads; an assay strip comprising at least one reagent well containing molecular diagnostic reagent volume configured to be combined with a nucleic acid volume of the set of nucleic acid volumes to produce at least one nucleic acid-reagent mixture; and a liquid handling system configured to transfer at least one biological sample combined with magnetic beads from the capture plate to the molecular diagnostic module, transfer at least one nucleic acid-reagent mixture from the assay strip back to the molecular diagnostic module.• U.S. Patent No. 9,050,594 at col. 3:14-28 (“The liquid handling system 250 then aspirates substantially all of each sample of the set of lysed biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate no, and dispenses the set of magnetic bead-samples into a microfluidic cartridge 210, aligned within a cartridge receiving module 140 of a molecular diagnostic module 130, and configured to be manipulated	REF	Contents	Tests per unit	Tests per carton	100100	NeuMoDx™ Cartridge	12	576	REF	Contents	400400, 400500 400600, 400700	NeuMoDx™ Lysis Buffer 1, 2, 3 and/or 4	100200	NeuMoDx™ Extraction Plate <i>Dried magnetic affinity microspheres, lytic enzymes, and sample process controls</i>	400100	NeuMoDx™ WASH Solution	400200	NeuMoDx™ RELEASE Solution	various	NeuMoDx™ test strip <i>(as applicable)</i>	235903	Hamilton CO-RE Tips (300 µL) with Filters (available from NeuMoDx or Hamilton)	235905	Hamilton CO-RE Tips (1000 µL) with Filters (available from NeuMoDx or Hamilton)
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Claim	Claim Language	Infringement Evidence
		<p>by the molecular diagnostic module 130.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 2:49-58 (“As shown in FIGS. 1A-1B and 7A, an embodiment of a system 100 for processing and detecting nucleic acids comprises: a capture plate 110 configured to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119; a molecular diagnostic module 130 comprising a microfluidic cartridge receiving module 140, heating and cooling subsystem 150, a magnet 160, a valve actuation subsystem 170, an optical subsystem 180; and an assay strip 190 configured to facilitate mixing of molecular diagnostic reagents with a nucleic acid volume.”) U.S. Patent No. 9,050,594 at FIG. 1A. <p>FIG. 1A</p>

Claim	Claim Language	Infringement Evidence
		<p>US9441219 (Exhibit 53)</p> <ul style="list-style-type: none"> Claim 14. The system of claim 8, further comprising a capture plate comprising a well containing a set of magnetic beads, a lysing reagent, and a sample process control, configured to be combined with the biological sample, wherein the capture plate facilitates production of a magnetic bead-sample from the biological sample and the set of magnetic beads; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the cartridge, and configured to transfer a nucleic acid volume processed from the magnetic bead-sample from the cartridge. U.S. Patent No. 9,441,219 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids. <p>US9604213 (Exhibit 30)</p> <ul style="list-style-type: none"> Claim 1. A system for processing and detecting nucleic acids in cooperation with a cartridge comprising a heating region defined at a first Surface, and a magnet housing region defined at a second surface in thermal communication with the first surface, the system comprising: a capture plate configured to facilitate combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate and separate nucleic acids from the set of magnetic beads, comprising: a cartridge platform configured to receive the cartridge and comprising a magnet receiving slot aligned with the second Surface during operation, a heater configured to transmit heat to the heating region at the first Surface during operation, and a magnet coupled to a magnet heating element that heats the

Claim	Claim Language	Infringement Evidence
		<p>magnet during operation with the magnet proximal the second surface, the magnet configured to pass through the magnet receiving slot into the magnet housing region during operation, thereby facilitating separation of a nucleic acid volume from the magnetic bead-sample and heating of the magnetic bead-sample in cooperation with the heater.</p> <ul style="list-style-type: none"> • Claim 8. The system of claim 1, further comprising a liquid handling system configured to transfer the magnetic bead sample from the capture plate to the molecular diagnostic module, and to aspirate the nucleic acid volume from the molecular diagnostic module. • U.S. Patent No. 9,604,213 col. 3:62-66 (“As shown in FIGS. 3A and 3B, the capture plate 110 comprises a capture plate substrate in comprising a set of wells 112 and a puncturable foil seal 115, and functions to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119.”)
1(f)	<p>wherein the lysing container is configured to receive the biological sample and configured to place the biological sample in contact with a lysing reagent to release polynucleotides from the biological sample into a lysate solution</p>	<p>The accused system comprises the lysing container configured to receive the biological sample and configured to place the biological sample in contact with a lysing reagent to release polynucleotides from the biological sample into a lysate solution.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p>  <p>Downloaded on 3/26/2019</p> <ul style="list-style-type: none"> • “Liquid Handling Processing A: Lysis and Capture. Dispensing lysis buffer. Dispensing lysis

Claim	Claim Language	Infringement Evidence																
		<p>buffer and patient specimen into extraction plate. The liquid handling robot delivers lysis buffer and patient specimen to the extraction plate, which has 24 independent wells which contain NeuDry affinity-coated paramagnetic beads. Each mixture is aspirated and dispensed five times to ensure homogeneity of the solution. During the transfer of patient specimen to the extraction plate the liquid handling robot uses pre-defined no-fly zones to reduce the potential of contamination.” <i>Id.</i> at 0:28-0:40.</p> <ul style="list-style-type: none">• <i>Id.</i> at 1:16 (showing binding of nucleic acids to paramagnetic beads). <div></div> <p>40600177 Rev-C-SDS-NeuMoDx-Lysis-Buffer-3-Final.pdf (Exhibit 70)</p> <table><tr><th colspan="4">Composition (Hazardous Components Only)</th></tr><tr><th>Name</th><th>Identifiers</th><th>%</th><th>GHS-US classification</th></tr><tr><td>Guanidine hydrochloride</td><td>CAS Number: 50-01-1</td><td>< 50%</td><td>Skin Irritation. 2; Eye Irritation. 2A</td></tr><tr><td>Sodium azide</td><td>CAS Number: 26628-22-8</td><td>< 0.1%</td><td>Not a hazardous substance or mixture at this concentration.</td></tr></table> <p>40600176 Rev-C-SDS -NeuMoDx-Lysis-Buffer-2-Final.pdf (Exhibit 69)</p>	Composition (Hazardous Components Only)				Name	Identifiers	%	GHS-US classification	Guanidine hydrochloride	CAS Number: 50-01-1	< 50%	Skin Irritation. 2; Eye Irritation. 2A	Sodium azide	CAS Number: 26628-22-8	< 0.1%	Not a hazardous substance or mixture at this concentration.
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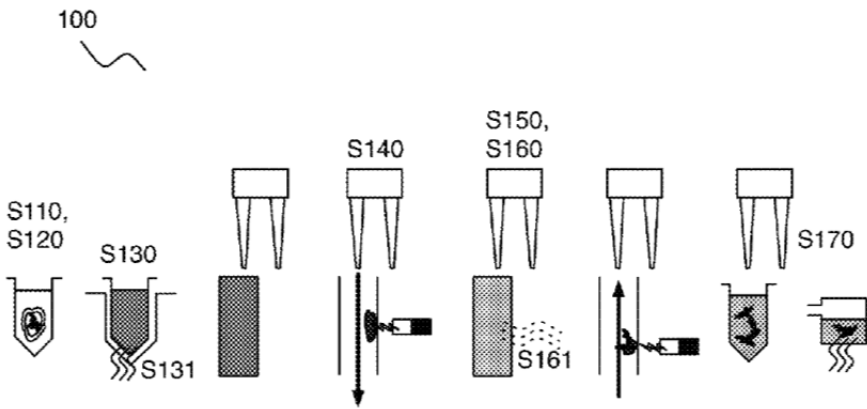
Claim	Claim Language	Infringement Evidence																																				
		<table><tr><th colspan="4">Composition (Hazardous Components Only)</th></tr><tr><th>Name</th><th>Identifiers</th><th>%</th><th>GHS-US classification</th></tr><tr><td>Guanidine hydrochloride</td><td>CAS Number: 50-01-1</td><td>< 50%</td><td>Skin Irritation. 2; Eye Irritation. 2A</td></tr><tr><td>Sodium azide</td><td>CAS Number: 26628-22-8</td><td>< 0.1%</td><td>Not a hazardous substance or mixture at this concentration.</td></tr></table> <p>40600175 Rev-C-SDS-NeuMoDx-Lysis-Buffer-1-Final.pdf (Exhibit 68)</p> <p>Mixtures</p> <p>Chemical Characterization: Mixture of a chemical and/or biological substances for <i>in vitro</i> diagnostic use.</p> <table><tr><th colspan="4">Composition (Hazardous Components Only)</th></tr><tr><th>Name</th><th>Identifiers</th><th>%</th><th>GHS-US classification</th></tr><tr><td>Guanidine hydrochloride</td><td>CAS Number: 50-01-1</td><td>< 50%</td><td>Skin Irritation. 2; Eye Irritation. 2A</td></tr><tr><td>Maleic acid</td><td>CAS Number: 110-16-7</td><td><1%</td><td>Not a hazardous substance or mixture at this concentration.</td></tr><tr><td>Sodium azide</td><td>CAS Number: 26628-22-8</td><td>< 0.1%</td><td>Not a hazardous substance or mixture at this concentration.</td></tr></table> <p>40600110 Rev-C-SDS-NeuMoDx-Extraction-Plate-FINAL-13Mar2019-1.pdf (Exhibit 93)</p>	Composition (Hazardous Components Only)				Name	Identifiers	%	GHS-US classification	Guanidine hydrochloride	CAS Number: 50-01-1	< 50%	Skin Irritation. 2; Eye Irritation. 2A	Sodium azide	CAS Number: 26628-22-8	< 0.1%	Not a hazardous substance or mixture at this concentration.	Composition (Hazardous Components Only)				Name	Identifiers	%	GHS-US classification	Guanidine hydrochloride	CAS Number: 50-01-1	< 50%	Skin Irritation. 2; Eye Irritation. 2A	Maleic acid	CAS Number: 110-16-7	<1%	Not a hazardous substance or mixture at this concentration.	Sodium azide	CAS Number: 26628-22-8	< 0.1%	Not a hazardous substance or mixture at this concentration.
Composition (Hazardous Components Only)																																						
Name	Identifiers	%	GHS-US classification																																			
Guanidine hydrochloride	CAS Number: 50-01-1	< 50%	Skin Irritation. 2; Eye Irritation. 2A																																			
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Maleic acid	CAS Number: 110-16-7	<1%	Not a hazardous substance or mixture at this concentration.																																			
Sodium azide	CAS Number: 26628-22-8	< 0.1%	Not a hazardous substance or mixture at this concentration.																																			

Claim	Claim Language	Infringement Evidence								
		<div>8.1 Occupational Exposure Limits</div> <table><tr><th>Chemical/Biological name</th><th>Limit</th><th>Control Parameters</th><th>Basis</th></tr><tr><td>Proteinase K</td><td>Not available</td><td>Not available</td><td>USA. Occupational Exposure Limits (OSHA). Table Z-1 limits for air contaminants.None</td></tr></table> <div>NeuMoDx_Novel_Dry_Reagent_2017.pdf (Exhibit 80)</div> <ul style="list-style-type: none">NMDx extraction plate is designed to be used on the NeuMoDx Molecular System to lyse bacteria and virus pathogens and capture DNA/RNA. It contains proteinase K, magnetic particles and DNA/RNA sample process control (SPC). The reagents were dried in a 24 well plate using the NMDx standard procedure, vacuum sealed foil pouch and stored at 40°C for accelerated study. The efficiency of the dried reagents was evaluated with two assays, Group B strep in Lim Broth and HCV in BaseMatrix. After equivalent to 1 yr at 22°C, no loss in activities was observed based on Ct and EPR values. <div>40600106_Rev-D-IFU-NeuMoDx-Lysis-Buffer-1-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 63)</div> <ul style="list-style-type: none">NeuMoDx™ Lysis Buffer 1 is a proprietary buffer used for the efficacious extraction of nucleic acids from unprocessed clinical specimens on the NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems (NeuMoDx™ System(s)) when used in conjunction with other NeuMoDx™ reagents such as NeuMoDx™ Extraction Plate, NeuMoDx™ WASH Solution, and the NeuMoDx™ RELEASE Solution, which are used for all tests processed on the NeuMoDx Systems. NeuMoDx Lysis Buffer 1 can be used for extraction of viral or bacterial DNA from human plasma and serum samples. <div>40600105_Rev-D-IFU-NeuMoDx-Lysis-Buffer-2-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 64)</div> <ul style="list-style-type: none">NeuMoDx™ Lysis Buffer 2 is a proprietary buffer used for the efficacious extraction of nucleic acids from unprocessed clinical specimens on the NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems (NeuMoDx™ System(s)) when used in conjunction with other NeuMoDx™ reagents such as NeuMoDx™ Extraction Plate, NeuMoDx™ WASH Solution, and the	Chemical/Biological name	Limit	Control Parameters	Basis	Proteinase K	Not available	Not available	USA. Occupational Exposure Limits (OSHA). Table Z-1 limits for air contaminants.None
Chemical/Biological name	Limit	Control Parameters	Basis							
Proteinase K	Not available	Not available	USA. Occupational Exposure Limits (OSHA). Table Z-1 limits for air contaminants.None							

Claim	Claim Language	Infringement Evidence
		<p>NeuMoDx™ RELEASE Solution, which are used for all tests processed on the NeuMoDx Systems. NeuMoDx Lysis Buffer 2 can be used for extraction of bacterial DNA from human urine samples.</p> <p>40600104_Rev-D-IFU-NeuMoDx-Lysis-Buffer-3-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 65)</p> <ul style="list-style-type: none"> The NeuMoDx™ Lysis Buffer 3 is a proprietary buffer used for the efficacious extraction of nucleic acids from unprocessed clinical specimens on the NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems (NeuMoDx™ System(s)) when used in conjunction with other NeuMoDx™ reagents such as NeuMoDx™ Extraction Plate, NeuMoDx™ WASH Solution, and the NeuMoDx™ RELEASE Solution, which are used for all tests processed on the NeuMoDx Systems. NeuMoDx Lysis Buffer 3 can be used for extraction of viral RNA from human plasma and serum samples. <p>40600103_Rev-D-IFU-NeuMoDx-Lysis-Buffer-4-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 66)</p> <ul style="list-style-type: none"> The NeuMoDx™ Lysis Buffer 4 is a proprietary lysis and binding buffer that when used in conjunction with NeuMoDx™ supplied consumables, NeuMoDx™ Extraction Plate, NeuMoDx™ WASH Solution, and NeuMoDx™ RELEASE Solution, enables the extraction of DNA from Gram-positive bacteria from clinical samples on the NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems (NeuMoDx™ System(s)). <p>40600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 20)</p> <ul style="list-style-type: none"> The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. <p>40600100_-Rev-D-IFU-NeuMoDx-WASH-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 58)</p> <ul style="list-style-type: none"> The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.

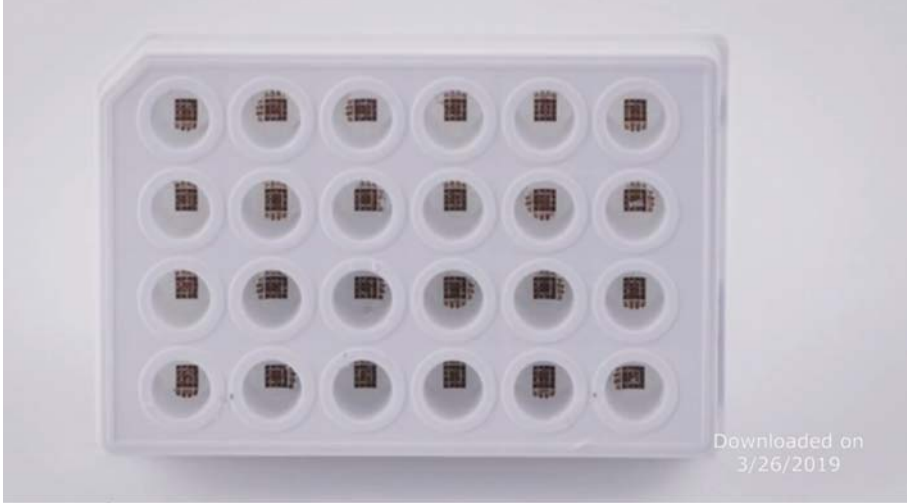
Claim	Claim Language	Infringement Evidence
		<p>An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres.</p> <p>40500098_D-IFU-NeuMoDx-Extraction-Plate-US-ONLY (Exhibit 59)</p> <ul style="list-style-type: none"> • “The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate lysis buffer in the NeuMoDx Extraction Plate and is subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres.” <i>Id.</i> at 1. <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> • The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx™ lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> • Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set

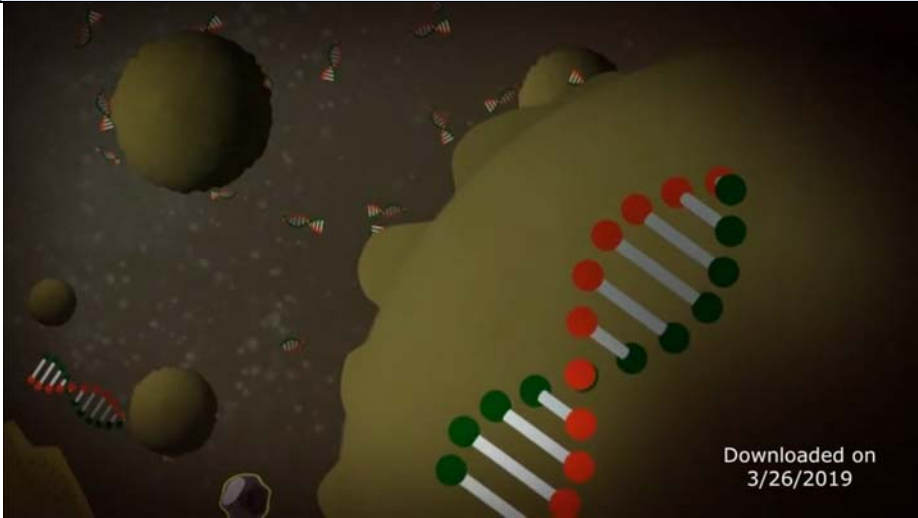
Claim	Claim Language	Infringement Evidence
		<p>of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 4. The method of claim 3, wherein incubating the moiety-sample mixture comprises heating the moiety-sample solution to a temperature in the range of 25-95° C. for 5-60 minutes, thus simultaneously lysing the biological sample and facilitating binding of nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles. • U.S. Patent No. 9,382,532 at col. 3:35-43 (“The method 100 can be performed in any container or process chamber that is configured to contain a suitable concentration of affinity moiety-coated microparticles, facilitate suitable buffer conditions to allow for binding (e.g., buffer conditions providing a suitably low pH), contain suitable amounts of proteolytic or other enzymes for effective lysis or removal of inhibitory substances, and provide suitable thermal conditions that collectively enable binding of nucleic acids to the affinity moiety-coated microparticles.”) • U.S. Patent No. 9,382,532 at 5:3-7 (“In Step S120, the process chamber can be any suitable vessel, as shown in FIG. 1A, or a suitable capture plate, such as that described in U.S. patent application Ser. No. 13/766,359, entitled “System and Method for Processing and Detecting Nucleic Acids”, as shown in FIG. 1B.”) • U.S. Patent No. 9,382,532 at FIG. 1B.

Claim	Claim Language	Infringement Evidence
		 <p data-bbox="1094 683 1241 716">FIGURE 1B</p> <p data-bbox="638 773 953 805">US9050594 (Exhibit 24)</p> <ul data-bbox="688 813 1976 1398" style="list-style-type: none"> • Claim 4. The system of claim 1, wherein the capture plate comprises a set of wells and a foil seal configured to seal each well of the set of wells, wherein each well in the set of wells contain a set of magnetic beads, a set of lysing reagents, and a sample process control. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) • U.S. Patent No. 9,050,594 col. 4:15-19 (“The set of wells 112 of the capture plate substrate 111 function to receive at least one biological sample with contain or are suspected of potentially

Claim	Claim Language	Infringement Evidence
		<p>containing nucleic acids, and to facilitate combination of the biological sample with a set of magnetic beads.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at col. 4:50-55 (“Each quantity of magnetic beads 119 may be accompanied by lysing reagents (e.g. proteinase K) and a sample process control comprising nucleic acid sequences for DNA and RNA, which function to lyse biological samples and to provide a mechanism by which sample process controls may be later detected to verify processing fidelity and assay accuracy.”) <p>US9540636 (Exhibit 54)</p> <ul style="list-style-type: none"> Claim 6. The method of claim 3, wherein incubating the moiety-sample mixture comprises heating the moiety-sample solution to a temperature above 25° C for at least 5 minutes, thus simultaneously lysing the biological sample and facilitating binding of nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles. Claim 14. A method for nucleic acid extraction, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles; mixing the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and target RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; and magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the microfluidic pathway of the cartridge. U.S. Patent No. 9,540,636 at col. 3:45-53 (“The method 100 can be performed in any container or process chamber that is configured to contain a suitable concentration of affinity moiety-coated microparticles, facilitate suitable buffer conditions to allow for binding (e.g., buffer conditions providing a suitably low pH), contain suitable amounts of proteolytic or other enzymes for effective lysis or removal of inhibitory substances, and provide suitable thermal conditions that collectively enable binding of nucleic acids to the affinity moiety-coated microparticles.”)

Claim	Claim Language	Infringement Evidence
1(g)	a plurality of magnetic binding particles disposed in the lysing container	<p>The accused system comprises a plurality of magnetic binding particles disposed in the lysing container.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “Liquid Handling Processing A: Lysis and Capture. Dispensing lysis buffer. Dispensing lysis buffer and patient specimen into extraction plate. The liquid handling robot delivers lysis buffer and patient specimen to the extraction plate, which has 24 independent wells which contain NeuDry affinity-coated paramagnetic beads. Each mixture is aspirated and dispensed five times to ensure homogeneity of the solution. During the transfer of patient specimen to the extraction plate the liquid handling robot uses pre-defined no-fly zones to reduce the potential of contamination.” <i>Id.</i> at 0:28-1:05 <i>Id.</i> at 0:40 (showing the extraction plate).

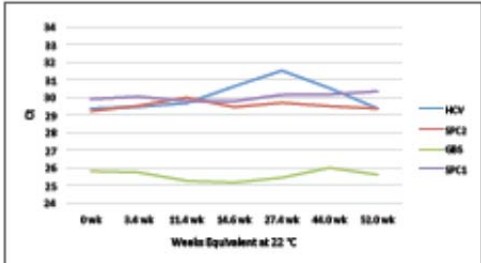
Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none"> • “Each extraction plate well is then heated independently for 10 minutes to ensure proper lysing and binding of the nucleic acids to the paramagnetic beads. The temperatures applied range from 37 degrees Celsius to 60 degrees Celsius, resulting in the flexibility to process a wide variety of DNA and RNA IVD and LDT tests simultaneously.” <i>Id.</i> at 1:05-1:35 • <i>Id.</i> at 1:16 (showing binding of nucleic acids to paramagnetic beads).

Claim	Claim Language	Infringement Evidence
		 <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound nucleic acid is eluted using the NeuMoDx™ RELEASE Solution. <p>40500098_D-IFU-NeuMoDx-Extraction-Plate-US-ONLY (Exhibit 59)</p> <ul style="list-style-type: none"> • “The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate lysis buffer in the NeuMoDx Extraction Plate and is subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres.” <i>Id.</i> at 1. • “The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE

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		<p>Solution.” <i>Id.</i> at 1.</p> <p>40600100_Rev-D-IFU-NeuMoDx-WASH-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 58)</p> <ul style="list-style-type: none"> The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 20)</p> <ul style="list-style-type: none"> The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600103_Rev-D-IFU-NeuMoDx-Lysis-Buffer-4-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 66)</p> <ul style="list-style-type: none"> The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.

Claim	Claim Language	Infringement Evidence
		<p>An aliquot of enriched Lim Broth is mixed with NeuMoDx Lysis Buffer 4 and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres dried in the NeuMoDx Extraction Plate.</p> <ul style="list-style-type: none"> • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600104_Rev-D-IFU-NeuMoDx-Lysis-Buffer-3-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 65)</p> <ul style="list-style-type: none"> • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600105_Rev-D-IFU-NeuMoDx-Lysis-Buffer-2-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 64)</p> <ul style="list-style-type: none"> • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600106_Rev-D-IFU-NeuMoDx-Lysis-Buffer-1-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 63)</p> <ul style="list-style-type: none"> • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600094_D-IFU-NeuMoDx-Cartidge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> • “NeuMoDx™ Cartridge: Instructions for Use...The released nucleic acids are captured by

Claim	Claim Language	Infringement Evidence
		<p>magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound nucleic acid is eluted using the NeuMoDx™ RELEASE Solution.”</p> <p>40600129_D-IFU-GBS-Test-Strip-US-only.pdf (Exhibit 60)</p> <ul style="list-style-type: none"> “NeuMoDx™ GBS Test Strip: Instructions for Use... The released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are loaded in to the NeuMoDx™ Cartridge where the unbound, non-DNA components are further washed away with NeuMoDx™ WASH Solution and the bound DNA is eluted using NeuMoDx™ RELEASE Solution.” <p>40600145_-Rev-D-IFU-NeuMoD-LDT-Master-Mix-DNA-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 67)</p> <ul style="list-style-type: none"> “NeuMoDx™ LDT Master Mix, DNA: Instructions for Use... Upon lysis, the released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound DNA is eluted using NeuMoDx™ RELEASE Solution.” <p>40600146_D-IFU-NeuMoDx-LDT-Master-Mix-RNA-US-ONLY (Exhibit 62)</p> <ul style="list-style-type: none"> “NeuMoDx™ LDT Master Mix, RNA: Instructions for Use... Upon lysis, the released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound RNA is eluted using NeuMoDx™ RELEASE Solution.” <p>NeuMoDx_Novel_Dry_Reagent_2017.pdf (Exhibit 81)</p> <ul style="list-style-type: none"> “Three types of molecular diagnostic reagents were dried using unique formulations of select excipients: 1) Extraction reagents including magnetic particles with a nucleic acid affinity matrix, lytic enzymes, and encapsulated DNA/process controls.”

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		<div><div><p>ACCELERATED STABILITY OF NMDx EXTRACTION PLATES</p><table data-bbox="783 647 1520 758"><thead><tr><th>Days at 40°C</th><th>0</th><th>6</th><th>20</th><th>24</th><th>48</th><th>64</th><th>77</th><th>81</th><th>Avg</th><th>St</th><th>%CV</th></tr></thead><tbody><tr><td>HCV</td><td>29.12</td><td>29.27</td><td>29.67</td><td>29.8</td><td>29.87</td><td>29.26</td><td>29.42</td><td>29.30</td><td>29.08</td><td>0.8a</td><td>2.8</td></tr><tr><td>SPC2</td><td>29.22</td><td>29.00</td><td>29.16</td><td>29.63</td><td>29.47</td><td>29.91</td><td>29.6a</td><td>29.3a</td><td>29.61</td><td>0.3</td><td>1</td></tr><tr><td>SPC1</td><td>2a.a4</td><td>2a.a4</td><td>2a.3a</td><td>2a.77</td><td>2a.3</td><td>2a.44</td><td>2a.1</td><td>2a.84</td><td>2a.a1</td><td>0.22</td><td>1.2</td></tr><tr><td>SPC1</td><td>29.82</td><td>29.24</td><td>29.94</td><td>29.1</td><td>29.47</td><td>29.31</td><td>29.18</td><td>29.44</td><td>29.2</td><td>0.21</td><td>0.7</td></tr><tr><td>Eq. at 22°C (hrs)</td><td>0</td><td>2.4</td><td>11.4</td><td>14.6</td><td>27.4</td><td>27.4</td><td>44</td><td>a2</td><td></td><td></td><td></td></tr></tbody></table><p>NMDx extraction plate is designed to be used on the NeuMoDx Molecular System to lyse bacteria and virus pathogens and capture DNA/RNA. It contains proteinase K, magnetic particles and DNA/RNA sample process control (SPC). The reagents were dried in a 24 well plate using the NMDx standard procedure, vacuum sealed foil pouch and stored at 40°C for accelerated study. The efficiency of the dried reagents was evaluated with two assays, Group B strep in Lim Broth and HCV in BaseMatrix. After equivalent to 1 yr at 22°C, no loss in activities was observed based on Ct and EPR values.</p></div></div> <div><p>US9050594 (Exhibit 24)</p><ul style="list-style-type: none">Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway</div>	Days at 40°C	0	6	20	24	48	64	77	81	Avg	St	%CV	HCV	29.12	29.27	29.67	29.8	29.87	29.26	29.42	29.30	29.08	0.8a	2.8	SPC2	29.22	29.00	29.16	29.63	29.47	29.91	29.6a	29.3a	29.61	0.3	1	SPC1	2a.a4	2a.a4	2a.3a	2a.77	2a.3	2a.44	2a.1	2a.84	2a.a1	0.22	1.2	SPC1	29.82	29.24	29.94	29.1	29.47	29.31	29.18	29.44	29.2	0.21	0.7	Eq. at 22°C (hrs)	0	2.4	11.4	14.6	27.4	27.4	44	a2			
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		<p>configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module. • Claim 24. The system of claim 23, further comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample, a lysing reagent, and a sample process control, wherein the capture plate facilitates production of at least one biological sample combined with magnetic beads; an assay strip comprising at least one reagent well containing molecular diagnostic reagent volume configured to be combined with a nucleic acid volume of the set of nucleic acid volumes to produce at least one nucleic acid-reagent mixture; and a liquid handling system configured to transfer at least one biological sample combined with magnetic beads from the capture plate to the molecular diagnostic module, transfer at least one nucleic acid-reagent mixture from the assay strip back to the molecular diagnostic module. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic

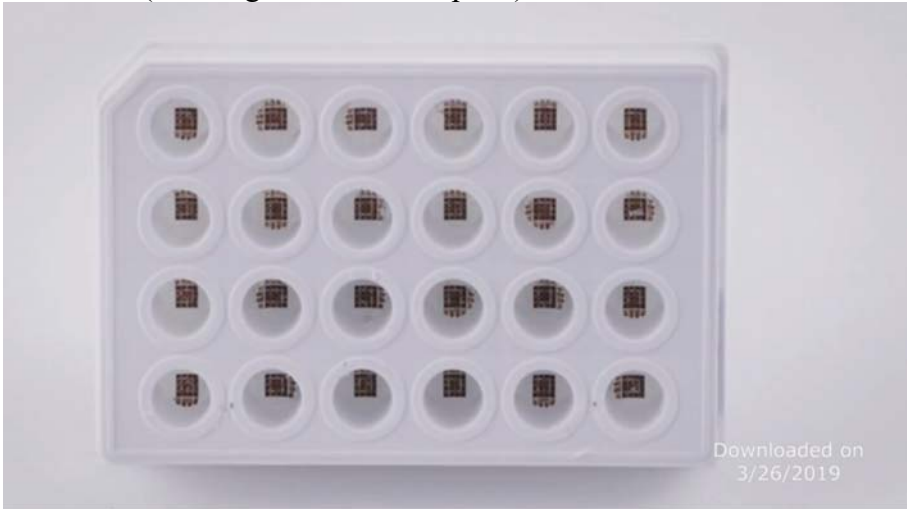
Claim	Claim Language	Infringement Evidence
		<p>acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”)</p> <p>US9339812 (Exhibit 26)</p> <ul style="list-style-type: none"> • Claim 2: The method of claim 1, further comprising combining the biological sample with a quantity of magnetic beads, to produce a magnetic bead-sample mixture, prior to dispensing the biological sample into the fluidic pathway through the sample port. • Claim 15. A method for processing and detecting nucleic acids from a set of biological samples with a cartridge having a set of fluidic pathways defined by an elastomeric layer, the method comprising: combining each biological sample of the set of biological samples with a quantity of magnetic beads to produce a set of nucleic acid-magnetic bead samples; aligning the cartridge at a cartridge platform of a molecular diagnostic module, the cartridge platform having a set of slots, and the molecular diagnostic module having a cam module contacting a set of pins aligned with the set of slots; transferring substantially all of each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways; moving the cam module by transitioning the actuator into an extended configuration, thereby displacing a subset of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the elastomeric layer to occlude at least one fluidic pathway of the set of fluidic pathways at a subset of occlusion positions for controlling a flow through the fluidic pathway; and detecting nucleic acids using a set of detection chambers coupled to the set of fluidic pathways. • Claim 18. The method of claim 15, wherein combining each biological sample of the set of biological samples with a quantity of magnetic beads comprises combining each biological sample of the set of biological samples with a quantity of magnetic beads treated to be at least one of positively charged, magnetic, paramagnetic, and supraparamagnetic [sic].” • Claim 29. A method for processing and detecting nucleic acids within a cartridge having a fluidic pathway including a set of occlusion positions defined by an elastomeric layer of the cartridge, the method comprising: aligning the cartridge at a cartridge platform of a molecular diagnostic module, the cartridge platform having a set of slots, and the molecular diagnostic module having

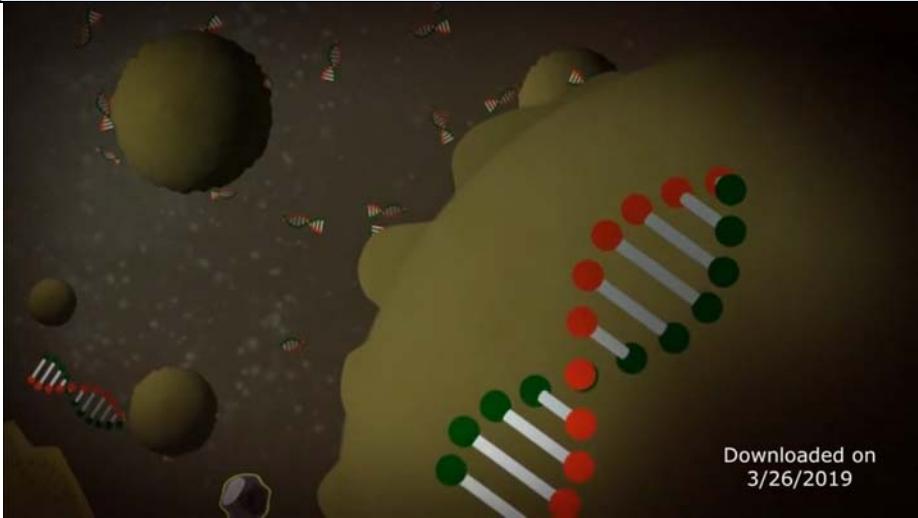
Claim	Claim Language	Infringement Evidence
		<p>a cam module contacting a set of pins aligned with the set of slots and an actuator that provides relative displacement between the cartridge platform and the set of pins; moving the cam module by transitioning the actuator into an extended configuration, thereby displacing a first sub-set of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the elastomeric layer to occlude the fluidic pathway at a first subset of the set of occlusion positions, thus defining a first truncated fluidic pathway passing through a magnetic field for controlling a flow through the fluidic pathway; capturing a sample of nucleic acids bound to magnetic beads within the first truncated fluidic pathway, by the magnetic field; and moving the cam module, thereby displacing a second subset of the set of pins through the set of slots of the cartridge platform and thereby manipulating the elastomeric layer to occlude the fluidic pathway, through the elastomeric layer, at a second subset of the set of occlusion positions, thus defining a second truncated fluidic pathway containing the sample of nucleic acids bound to magnetic beads.</p> <ul style="list-style-type: none"> U.S Patent No. 9,339,812 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety

Claim	Claim Language	Infringement Evidence
		<p>solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the microfluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20 uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction.</p> <p>US9441219 (Exhibit 53)</p> <ul style="list-style-type: none"> • Claim 7: The molecular diagnostic module of claim 1, further comprising: a capture plate comprising a well containing a set of magnetic beads, a lysing reagent, and a sample process control, configured to be combined with the biological sample, wherein the capture plate facilitates production of a magnetic bead-sample from the biological sample and the set of magnetic beads; an assay strip comprising a reagent well containing a molecular diagnostic reagent volume configured to be combined with the nucleic acid volume processed from the magnetic-bead sample, thereby generating a nucleic acid-reagent mixture; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the cartridge, transfer the nucleic acid volume from the cartridge to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip back to the cartridge. • Claim 14. The system of claim 8, further comprising a capture plate comprising a well containing a set of magnetic beads, a lysing reagent, and a sample process control, configured to be combined with the biological sample, wherein the capture plate facilitates production of a magnetic bead-sample from the biological sample and the set of magnetic beads; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the cartridge, and configured to transfer a nucleic acid volume processed from the magnetic bead-sample from the cartridge.

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> U.S. Patent No. 9,441,219 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation Subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical Subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) <p>US9604213 (Exhibit 30)</p> <ul style="list-style-type: none"> Claim 1: A system for processing and detecting nucleic acids in cooperation with a cartridge comprising a heating region defined at a first surface, and a magnet housing region defined at a second surface in thermal communication with the first surface, the system comprising: a capture plate configured to facilitate combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate and separate nucleic acids from the set of magnetic beads, comprising: a cartridge platform configured to receive the cartridge and comprising a magnet receiving slot aligned with the second surface during operation, a heater configured to transmit heat to the heating region at the first surface during operation, and a magnet coupled to a magnet heating element that heats the magnet during operation with the magnet proximal the second surface, the magnet configured to pass through the magnet receiving slot into the magnet housing region during operation, thereby facilitating separation of a nucleic acid volume from the magnetic bead-sample and heating of the magnetic bead-sample in cooperation with the heater. U.S. Patent No. 9,604,213 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving

Claim	Claim Language	Infringement Evidence
		<p>module, a heating/cooling Subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation Subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical Subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay Strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,604,213 at col. 3:62-66 (“As shown in FIGS. 3A and 3B, the capture plate 110 comprises a capture plate substrate in comprising a set of wells 112 and a puncturable foil seal 115, and functions to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119.”) <p>US1001888 (Exhibit 55)</p> <ul style="list-style-type: none"> • Claim 14: A method for processing and detecting nucleic acids from a sample with a cartridge including a fluidic pathway passing between a heating region of the cartridge and a magnet housing region of the cartridge, wherein the method comprises: with a liquid handling system, combining the sample with a quantity of magnetic beads to produce a nucleic acid-magnetic bead sample; with the liquid handling system, transferring the nucleic acid-magnetic bead sample to the fluidic pathway of the cartridge; and contemporaneously transmitting heat through the heating region, by way of a heater, and transmitting heat through the magnet housing region, by way of a magnet heating element coupled to a magnet, thereby facilitating capture of nucleic acids of the sample at the fluidic pathway of the cartridge.
1(h)	the plurality of magnetic binding particles comprising polycationic molecules on the surfaces thereof	<p>The accused system comprises the plurality of magnetic binding particles comprising polycationic molecules on the surfaces thereof.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMoDx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <p>On information and belief, the accused system comprises the plurality of magnetic binding particles comprising polycationic molecules on the surfaces thereof.</p>

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • “Liquid Handling Processing A: Lysis and Capture. Dispensing lysis buffer. Dispensing lysis buffer and patient specimen into extraction plate. The liquid handling robot delivers lysis buffer and patient specimen to the extraction plate, which has 24 independent wells which contain NeuDry affinity-coated paramagnetic beads. Each mixture is aspirated and dispensed five times to ensure homogeneity of the solution. During the transfer of patient specimen to the extraction plate the liquid handling robot uses pre-defined no-fly zones to reduce the potential of contamination.” <i>Id.</i> at 0:28-1:05 • <i>Id.</i> at 0:40 (showing the extraction plate).  <p style="text-align: right; font-size: small;">Downloaded on 3/26/2019</p> <ul style="list-style-type: none"> • “Each extraction plate well is then autonomously heated for as little as six minutes to ensure proper lysing and binding of the nucleic acids to the paramagnetic beads. The temperatures applied range from 37° C to over 90° C, resulting in the flexibility to process a wide variety of DNA and RNA IVD and LDT tests simultaneously.” 1:07-1:32 • <i>Id.</i> at 1:16 (showing binding of nucleic acids to paramagnetic beads).

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		 <p data-bbox="636 816 1965 889"><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul data-bbox="688 898 1965 1369" style="list-style-type: none"> • “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieving [sic] optimal operational and clinical performance for our customers and their patients.” • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents.

Claim	Claim Language	Infringement Evidence
		<p>40500098_D-IFU-NeuMoDx-Extraction-Plate-US-ONLY (Exhibit 59)</p> <ul style="list-style-type: none"> • “Each 24-well NeuMoDx Extraction Plate contains dried, room-temperature stable reagents including proprietary coated magnetic microspheres, a lytic enzyme, and RNA and DNA Sample Process Controls. Components within the extraction plate work in conjunction with the appropriate NeuMoDx lysis buffer to lyse cells in a temperature dependent manner and bind the nucleic acid while reducing activity of any nucleases present in clinical samples. The Sample Process Controls bind to the magnetic microspheres at the same time as the target nucleic acid, and are carried throughout the extraction procedure, serving as internal controls to monitor for any inefficiencies in the extraction process and presence of PCR interference substances.” <i>Id.</i> at 1. • “The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution.” <i>Id.</i> at 1. <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound nucleic acid is eluted using the NeuMoDx™ RELEASE Solution. <p>40600104_Rev-D-IFU-NeuMoDx-Lysis-Buffer-3-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 65)</p> <ul style="list-style-type: none"> • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600105_Rev-D-IFU-NeuMoDx-Lysis-Buffer-2-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 64)</p> <ul style="list-style-type: none"> • The released nucleic acids are captured by magnetic affinity microspheres and these

Claim	Claim Language	Infringement Evidence
		<p>microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution.</p> <p>40600106_ Rev-D-IFU-NeuMoDx-Lysis-Buffer-1-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 63)</p> <ul style="list-style-type: none"> • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600094_D-IFU-NeuMoDx-Cartidge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> • “NeuMoDx™ Cartridge: Instructions for Use...The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound nucleic acid is eluted using the NeuMoDx™ RELEASE Solution.” <p>40600129_D-IFU-GBS-Test-Strip-US-only.pdf (Exhibit 60)</p> <ul style="list-style-type: none"> • “NeuMoDx™ GBS Test Strip: Instructions for Use...The released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are loaded in to the NeuMoDx™ Cartridge where the unbound, non-DNA components are further washed away with NeuMoDx™ WASH Solution and the bound DNA is eluted using NeuMoDx™ RELEASE Solution.” <p>40600145_-Rev-D-IFU-NeuMoD-LDT-Master-Mix-DNA-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 67)</p> <ul style="list-style-type: none"> • “NeuMoDx™ LDT Master Mix, DNA: Instructions for Use...Upon lysis, the released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bund nucleic acids, are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution

Claim	Claim Language	Infringement Evidence
		<p>and the bound DNA is eluted using NeuMoDx™ RELEASE Solution.”</p> <p>40600146_D-IFU-NeuMoDx-LDT-Master-Mix-RNA-US-ONLY (Exhibit 62)</p> <ul style="list-style-type: none"> • “NeuMoDx™ LDT Master Mix, RNA: Instructions for Use... Upon lysis, the released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound RNA is eluted using NeuMoDx™ RELEASE Solution.” <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> • Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10. • Claim 2. The method of claim 1, wherein receiving the binding moiety solution, comprising the set of affinity moiety-coated microparticles, within the process chamber comprises receiving a set of magnetic microparticles, each magnetic microparticle modified with an amine-reactive ester functional group configured to react with one of a set of amine groups of a molecule of

Claim	Claim Language	Infringement Evidence
		<p>Polypropylenimine tetramine dendrimer Generation 1.</p> <ul style="list-style-type: none"> Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the microfluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20 uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction. Claim 19. A method for nucleic acid isolation from a biological sample, comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution includes a set of affinity moiety-coated microparticles, comprising a set of microparticles amide-bonded to at least one of poly(allylamine) of molecular weight <30,000 Da and Polypropylenimine tetramine dendrimer Generation 1; producing a moiety-sample mixture upon combination of the binding moiety solution with the biological sample; producing a set of moiety-bound nucleic acid particles upon incubation of the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the

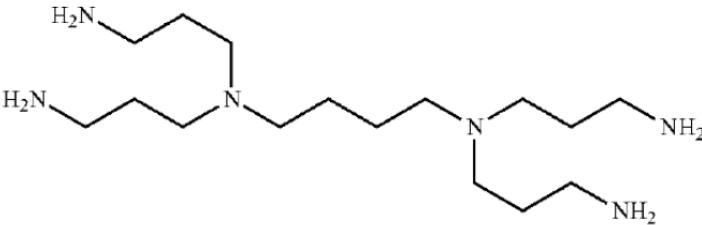
Claim	Claim Language	Infringement Evidence
		<p>cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of the set of pins includes reversing displacement of at least one pin of the first subset of the set of pins, and reversing occlusion of a portion of the fluidic pathway.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at 9:11-15 (“Specifically, at low pH, the affinity moieties are positively charged, which results in attraction to negatively charged nucleic acids; however, at high pH, the affinity moieties are negatively charged, which results in repulsion of negatively charged nucleic acids.”) • U.S. Patent No. 9,382,532 at 11:30-40 (“Nucleic acid molecules are typically negatively charged at standard processing conditions. In such processes, positively charged moieties can capture and retain the negatively charged nucleic acid molecules; however, the positively charged moieties can bind too strongly with target nucleic acids leading to an irreversible process whereby the bound nucleic acid cannot be released into the solution for further processing/analysis. Two novel molecules that are capable of binding nucleic acid in a reversible manner are described below, wherein the reversible binding is modulated by changing the pH of the environment.”) • U.S. Patent No. 9,382,532 at 11:43-53 (“Poly(allylamine), or PAA, is a cationic poly electrolyte prepared by the polymerization of allylamine. Allylamine is an organic compound with the formula C₃H₅NH₂ . An exemplary PAA molecule has the following formula: <div data-bbox="743 1015 955 1193" data-label="Chemical-Block"> <p>The diagram shows the chemical structure of Poly(allylamine) (PAA). It consists of a repeating unit enclosed in brackets with a subscript 'n'. The backbone is a carbon-carbon single bond. One carbon atom is bonded to a hydrogen atom (H) and a hydrogen atom (H). The other carbon atom is bonded to a hydrogen atom (H) and an amino group (NH₂).</p> </div> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at 12:11-27 (“Polypropylenimine tetramine dendrimer Generation 1, or DABAM Generation 1, is a cationic polyelectrolyte dendrimer. Dendrimers are repetitively branched molecules. A dendrimer is typically symmetric around a core, and often adopts a spherical three-dimensional structure. An exemplary DABAM molecule has the

Claim	Claim Language	Infringement Evidence
		<div data-bbox="1031 248 1732 500" data-label="Chemical-Block"> </div> <p>following formula:</p> <ul style="list-style-type: none"> U.S. Patent No. 9,382,532 at 12:51-61 (“The affinity moieties, such as the PAA and DABAM described in Section 2.1 and 2.2, can be immobilized on a suitable substrate to facilitate subsequent capture of target nucleic acids bound to the substrate (e.g., by magnetic separation, size-based separation, density-based separation, or focusing).”) U.S. Patent No. 9,382,532 at 12:62-13:13 (“As shown in FIG. 3, a method 200 for coupling the microparticles with the affinity moieties comprises activating carboxylated microparticles with EDAC 5210 to form a set of microparticle-reactive ester compounds; treating the set of microparticle-reactive ester compounds with an N-Hydroxysuccinimide to form a set of microparticle-amine reactive ester compounds S220, combining the set of microparticle-amine reactive ester compounds with a set of affinity moieties selected from the group comprising PAA and DABAM S230 to produce a microparticle-moiety solution; and washing the microparticle-moiety solution, thereby producing a set of microparticles covalently bonded to the set of affinity moieties by amide bonds S240.”) U.S. Patent No. 9,382,532 at 13:14-28 (“In a specific example, as shown in FIG. 3, the method 200 comprises activating magnetic carboxylated microparticles with EDAC in Step S110 to form a set of magnetic microparticle-reactive ester compounds; treating the set of magnetic microparticle-reactive ester compounds with a N-Hydroxysulfosuccinimide to form a set of microparticle-amine reactive ester compounds S220; combining the set of microparticle-amine reactive ester compounds with a set of affinity moieties selected from the group comprising PAA of molecular weight less than 30,000 Da and DABAM of generation less than two S230 to produce a microparticle-moiety solution; and repeatedly washing the microparticle-moiety solution, thereby producing a set of magnetic microparticles covalently bonded to the set of affinity moieties by amide bonds S240.”) U.S. Patent No. 9,382,532 at 13:42-45 (“A first example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, cerebrospinal fluid (CSF) as a

Claim	Claim Language	Infringement Evidence
		<p>representative biological sample, and Enterovirus (EV) viral particles as the model target.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at 14:5-9 (“A second example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, M4 transport medium containing a nasal swab (donor) as a representative biological sample, and Enterovirus (EV) viral particles as the model target.”) • U.S. Patent No. 9,382,532 at 14:41-45 (“A third example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, Universal Transport Medium (UTM) containing a nasal swab (donor) as a representative biological sample, and Enterovirus (EV) viral particles as the model target.”) • U.S. Patent No. 9,382,532 at 15:8-12 (“A fourth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, M4 transport medium containing nasal swab (donor) as a representative biological sample, and Enterovirus (EV) viral particles as the model target.”) • U.S. Patent No. 9,382,532 at 15:58-63 (“A fifth example of the method 100 comprises using DABAM affinity moieties coated onto magnetic microparticles, Human Urine (donor), Human Plasma and Buccal Swab (donor) as representative biological sample matrices, and Group B Streptococcus (GBS) DNA (ATCC, Virginia) as the model target.”) • U.S. Patent No. 9,382,532 at 16:29-32 (“A sixth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, Human Urine (donor) as a representative biological sample, and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,382,532 at 16:61-65 (“A seventh example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, Human Plasma (donor, obtained from Bioreclamation, Inc.) as a representative biological sample, and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,382,532 at 17:27-31 (“An eighth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, simulated swab specimens as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,382,532 at 17:60-64 (“A ninth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, simulated swab transport media specimens as representative biological samples and Group B Streptococcus (GBS) DNA at the model target.”) • U.S. Patent No. 9,382,532 at 18:31-34 (“A tenth example of the method 100 comprises using

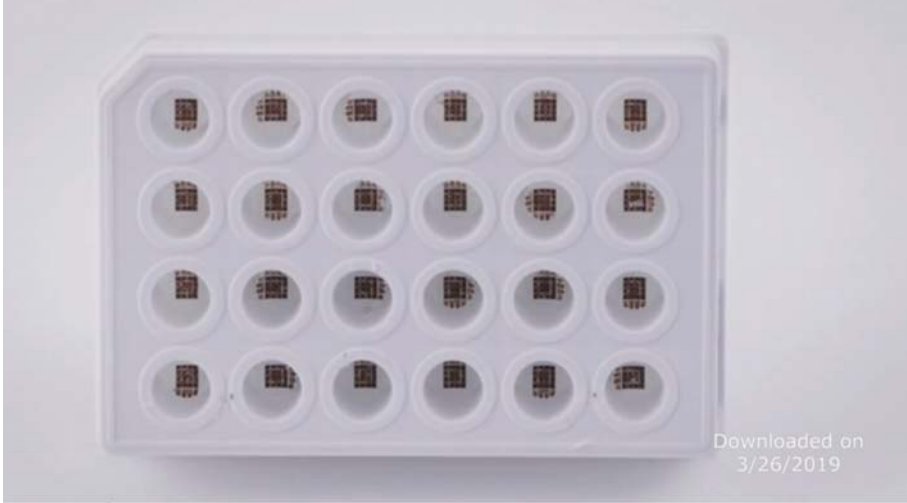
Claim	Claim Language	Infringement Evidence
		<p>PAA affinity moieties coated onto magnetic microparticles, whole blood as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at 19:12-15 (“An eleventh example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, Urine (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,382,532 at 19:46-49 (“A twelfth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, plasma (donor) as a representative biological sample, and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,382,532 at 20:6-11 (“A thirteenth example of the method 100, demonstrating the effect of binding time, comprises using PAA affinity moieties coated onto magnetic microparticles, Human Plasma (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA (ATCC, Virginia) as the model target.”) • U.S. Patent No. 9,382,532 at 20:33-38 (“A fourteenth example of the method 100, demonstrating the effect of binding temperature, comprises using PAA affinity moieties coated onto magnetic microparticles, Human Plasma (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA (ATCC, Virginia) as the model target.”) • U.S. Patent No. 9,382,532 at 21:23-27 (“A fifteenth example of the method 100, demonstrating the effect of binding temperature, comprises using PAA affinity moieties coated onto magnetic microparticles, Urine (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,382,532 at 21:58-62 (“A sixteenth example of the method 100, demonstrating the use of two different elution solutions, comprises using PAA affinity moieties coated onto magnetic microparticles, Human Urine (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,382,532 at 22:31-37 (“A seventeenth example of the method 100, demonstrating the use of nucleic acid isolation reagents for total nucleic acid (TNA) extraction, comprises using PAA affinity moieties coated onto magnetic microparticles, M4 transport media as a representative biological sample, and Enterovirus (EV) viral particles as the model RNA target and Group B Streptococcus DNA as model DNA target.”) <p>US9540636 (Exhibit 54)</p> <ul style="list-style-type: none"> • Claim 2. The method of claim 1, wherein the set of affinity moiety-coated microparticles

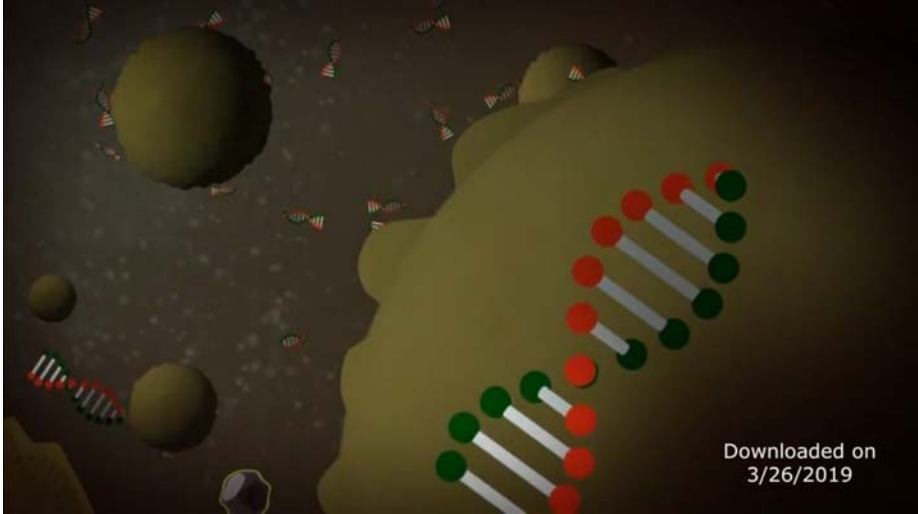
Claim	Claim Language	Infringement Evidence
		<p>comprises a set of magnetic microparticles, and wherein receiving the binding moiety solution, comprising the set of affinity moiety-coated microparticles, within the process chamber comprises receiving the set of magnetic microparticles, each magnetic microparticle modified with an amine-reactive ester functional group configured to react with one of a set of amine groups of a molecule of Polypropylenimine tetramine dendrimer Generation 1.</p> <ul style="list-style-type: none"> • Claim 19. The method of claim 17, wherein the set of affinity moiety-coated microparticles comprises a set of microparticles amide-bonded to at least one of the Poly(allylamine) of molecular weight <40,000 Da and the Polypropylenimine tetramine dendrimer Generation 1. • U.S. Patent No. 9,540,636 at col. 11:51-61 (“Nucleic acid molecules are typically negatively charged at standard processing conditions. In such processes, positively charged moieties can capture and retain the negatively charge nucleic acid molecules; however, the positively charged moieties can bind too strongly with target nucleic acids leading to an irreversible process whereby the bound nucleic acid cannot be released into the solution for further processing/analysis. Two novel molecules that are capable of binding nucleic acid in a reversible manner are described below, wherein the reversible binding is modulated by changing the pH of the environment.”) • U.S. Patent No. 9,540,636 at col. 11:65-66 (“Poly(allylmine), or PAA, is a cationic polyelectrolyte prepared by the polymerization of allylamine.”) <div data-bbox="842 959 993 1109" data-label="Chemical-Block"> <p>The diagram shows a chemical structure of a poly(allylamine) (PAA) polymer chain. It consists of a backbone of carbon atoms connected by single bonds, with alternating methylene groups and nitrogen-containing side groups. The repeating unit is shown in brackets with a subscript 'n'. The side group is a -CH2-NH2 group, where the nitrogen atom is bonded to a hydrogen atom. The backbone is represented by a zigzag line, with the repeating unit being -[CH2-CH(NH2)]-.</p> </div> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 12:36-38 (“Polypropylenimine tetramine dendrimer Generation 1, or DABAM Generation 1, is a cationic polyelectrolyte dendrimer.”)

Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 14:9-12 (A first example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, cerebrospinal fluid (CSF) as a representative biological sample, and Enterovirus (EV) viral particles as the model target.”) • U.S. Patent No. 9,540,636 at col. 14:44-48 (“A second example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, M4 transport medium containing a nasal Swab (donor) as a representative biological sample, and Enterovirus (EV) viral particles as the model target.”) • U.S. Patent No. 9,540,636 at col. 15:18-22 (“A third example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, Universal Transport Medium (UTM) containing a nasal swab (donor) as a representative biological sample, and Enterovirus (EV) viral particles as the model target.”) • U.S. Patent No. 9,540,636 at col. 15:56-60 (“A fourth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, M4 transport medium containing nasal Swab (donor) as a representative biological sample, and Enterovirus (EV) viral particles as the model target.”) • U.S. Patent No. 9,540,636 at col. 16:43-48 (“A fifth example of the method 100 comprises using DABAM affinity moieties coated onto magnetic microparticles, Human Urine (donor), Human Plasma and Buccal Swab (donor) as representative biological sample matrices, and Group B Streptococcus (GBS) DNA (ATCC, Virginia) as the model target.”) • U.S. Patent No. 9,540,636 at col. 17:19-22 (“A sixth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, Human Urine (donor) as a representative biological sample, and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,540,636 at col. 17:56-60 (“A seventh example of the method 100 comprises

Claim	Claim Language	Infringement Evidence
		<p>using PAA affinity moieties coated onto magnetic microparticles, Human Plasma (donor, obtained from Bioreclamation, Inc.) as a representative biological sample, and Group B Streptococcus (GBS) DNA as the model target.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 18:27-31 (“An eighth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, simulated Swab specimens as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,540,636 at col. 18:65-19:2 (“A ninth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, simulated Swab transport media specimens as representative biological samples and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,540,636 at col. 19:41-44 (“A tenth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, whole blood as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,540,636 at col. 20:27-30 (“An eleventh example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, Urine (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,540,636 at col. 20:66-21:2 (“A twelfth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, plasma (donor) as a representative biological sample, and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,540,636 at col. 21:31-36 (“A thirteenth example of the method 100, demonstrating the effect of binding time, comprises using PAA affinity moieties coated onto magnetic microparticles, Human Plasma (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA (ATCC, Virginia) as the model target.”) • U.S. Patent No. 9,540,636 at col. 21:61-66 (“A fourteenth example of the method 100, demonstrating the effect of binding temperature, comprises using PAA affinity moieties coated onto magnetic microparticles, Human Plasma (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA (ATCC, Virginia) as the model target.”) • U.S. Patent No. 9,540,636 at col. 22:56-60 (“A fifteenth example of the method 100, demonstrating the effect of binding temperature, comprises using PAA affinity moieties coated onto magnetic microparticles, Urine (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target.”)

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> U.S. Patent No. 9,540,636 at col. 23:30-35 (“A sixteenth example of the method 100, demonstrating the use of two different elution solutions, comprises using PAA affinity moieties coated onto magnetic microparticles, Human Urine (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target.”) U.S. Patent No. 9,540,636 at col. 24:10-16 (“A seventeenth example of the method 100, demonstrating the use of nucleic acid isolation reagents for total nucleic acid (TNA) extraction, comprises using PAA affinity moieties coated onto magnetic microparticles, M4 transport media as a representative biological sample, and Enterovirus (EV) viral particles as the model RNA target and Group B Streptococcus DNA as model DNA target.”)
1(i)	wherein the plurality of magnetic binding particles are configured to retain at least a portion of the polynucleotides on the surface thereof in the lysate solution at a pH of 8.5 or less	<p>The accused system comprises the plurality of magnetic binding particles are configured to retain at least a portion of the polynucleotides on the surface thereof in the lysate solution at a pH of 8.5 or less.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <p>“The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge.”</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> <i>Id.</i> at 0:40 (showing the extraction plate).

Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none"> • “Each extraction plate well is then autonomously heated for as little as six minutes to ensure proper lysing and binding of the nucleic acids to the paramagnetic beads. The temperatures applied range from 37° C to over 90° C, resulting in the flexibility to process a wide variety of DNA and RNA IVD and LDT tests simultaneously.” 1:07-1:32 • <i>Id.</i> at 1:16 (showing binding of nucleic acids to paramagnetic beads).

Claim	Claim Language	Infringement Evidence
		 <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound nucleic acid is eluted using the NeuMoDx™ RELEASE Solution. <p>40500098_D-IFU-NeuMoDx-Extraction-Plate-US-ONLY (Exhibit 59)</p> <ul style="list-style-type: none"> • “The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate lysis buffer in the NeuMoDx Extraction Plate and is subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres.” <i>Id.</i> at 1. • “The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE

Claim	Claim Language	Infringement Evidence
		<p>Solution.” <i>Id.</i> at 1.</p> <p>40600100_Rev-D-IFU-NeuMoDx-WASH-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 58)</p> <ul style="list-style-type: none"> The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 20)</p> <ul style="list-style-type: none"> The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600103_Rev-D-IFU-NeuMoDx-Lysis-Buffer-4-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 66)</p> <ul style="list-style-type: none"> The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.

Claim	Claim Language	Infringement Evidence
		<p>An aliquot of enriched Lim Broth is mixed with NeuMoDx Lysis Buffer 4 and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres dried in the NeuMoDx Extraction Plate.</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600104_Rev-D-IFU-NeuMoDx-Lysis-Buffer-3-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 65)</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600105_Rev-D-IFU-NeuMoDx-Lysis-Buffer-2-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 64)</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600106_Rev-D-IFU-NeuMoDx-Lysis-Buffer-1-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 63)</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600094_D-IFU-NeuMoDx-Cartidge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> “NeuMoDx™ Cartridge: Instructions for Use...The released nucleic acids are captured by

Claim	Claim Language	Infringement Evidence
		<p>magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound nucleic acid is eluted using the NeuMoDx™ RELEASE Solution.”</p> <p>40600129_D-IFU-GBS-Test-Strip-US-only.pdf (Exhibit 60)</p> <ul style="list-style-type: none"> • “NeuMoDx™ GBS Test Strip: Instructions for Use...The released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are loaded in to the NeuMoDx™ Cartridge where the unbound, non-DNA components are further washed away with NeuMoDx™ WASH Solution and the bound DNA is eluted using NeuMoDx™ RELEASE Solution.” <p>40600145_-Rev-D-IFU-NeuMoD-LDT-Master-Mix-DNA-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 67)</p> <ul style="list-style-type: none"> • “NeuMoDx™ LDT Master Mix, DNA: Instructions for Use...Upon lysis, the released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bund nucleic acids, are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound DNA is eluted using NeuMoDx™ RELEASE Solution.” <p>40600146_D-IFU-NeuMoDx-LDT-Master-Mix-RNA-US-ONLY (Exhibit 62)</p> <ul style="list-style-type: none"> • “NeuMoDx™ LDT Master Mix, RNA: Instructions for Use...Upon lysis, the released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound RNA is eluted using NeuMoDx™ RELEASE SOLUTION.” <p>NeuMoDx_Novel_Dry_Reagent_2017.pdf (Exhibit 80)</p> <ul style="list-style-type: none"> • “Three types of molecular diagnostic reagents were dried using unique formulations of select excipients: 1) Extraction reagents including magnetic particles with a nucleic acid affinity matrix, lytic enzymes, and encapsulated DNA/process controls.”

Claim	Claim Language	Infringement Evidence
		40600175 REV-C-SDS-NeuMoDx-Lysis-Buffer-1-Final.pdf (Exhibit 68) <div><div>9.1General Information</div><div><div>Form:</div><div>Liquid</div></div><div><div>Color:</div><div>Clear, with a slightly yellow tinge</div></div><div><div>Odor:</div><div>odorless</div></div><div><div>Odor Threshold:</div><div>Not determined</div></div><div><div>pH Value at 20°C (68°F):</div><div>4.45 – 4.9</div></div><div><div>Melting point/melting range:</div><div>Not determined</div></div></div>
		40600100 -Rev-D-IFU-NeuMoDx-WASH-Solution US-ONLY-FINAL-25Oct2018.pdf (Exhibit 58) <div><div><div>General Information</div></div><div><div>Form:</div><div>Liquid</div></div><div><div>Color:</div><div>Clear</div></div><div><div>Odor:</div><div>Odorless</div></div><div><div>pH Value at 20°C (68°F)</div><div>pH 7.0-8.1</div></div><div><div>melting point/melting range:</div><div>Not determined</div></div></div>
		40600176 Rev-C-SDS -NeuMoDx-Lysis-Buffer-2-Final.pdf (Exhibit 69) <div><div>9.1General Information</div><div><div>Form:</div><div>Liquid</div></div><div><div>Color:</div><div>Clear, with a slightly yellow tinge</div></div><div><div>Odor:</div><div>odorless</div></div><div><div>Odor Threshold:</div><div>Not determined</div></div><div><div>pH Value at 20°C (68°F):</div><div>4.2 – 5.2</div></div><div><div>Melting point/melting range:</div><div>Not determined</div></div></div>
		40600177 Rev-C-SDS-NeuMoDx-Lysis-Buffer-3-Final.pdf (Exhibit 70)

Claim	Claim Language	Infringement Evidence
		<p>9.1 General Information</p> <p>Form: Liquid</p> <p>Color: Clear, with a slightly yellow tinge</p> <p>Odor: Odorless</p> <p>Odor Threshold: Not determined</p> <p>pH Value at 20°C (68°F): 4.9 – 5.1</p> <p>Melting point/melting range: Not determined</p> <p>40600112_Rev-B-SDS-NeuMoDx-Lysis-Buffer-4-FINAL.pdf (Exhibit 71)</p> <p>9.1 General Information</p> <p>Form: Liquid</p> <p>Color: Clear, with a slightly yellow tinge</p> <p>Odor: odorless</p> <p>Odor Threshold: Not determined</p> <p>pH Value at 20°C (68°F): 4.45 – 4.9</p> <p>Melting point/melting range: Not determined</p> <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the

Claim	Claim Language	Infringement Evidence
		<p>set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module. • Claim 24. The system of claim 23, further comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample, a lysing reagent, and a sample process control, wherein the capture plate facilitates production of at least one biological sample combined with magnetic beads; an assay strip comprising at least one reagent well containing molecular diagnostic reagent volume configured to be combined with a nucleic acid volume of the set of nucleic acid volumes to produce at least one nucleic acid-reagent mixture; and a liquid handling system configured to transfer at least one biological sample combined with magnetic beads from the capture plate to the molecular diagnostic module, transfer at least one nucleic acid-reagent mixture from the assay strip back to the molecular diagnostic module. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving

Claim	Claim Language	Infringement Evidence
		<p>module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”)</p> <p>US9540636 (Exhibit 54)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col.14:12-16 (“In the first example, 200 uL of CSF was spiked with 2 ul of EV viral particle lysate and then mixed with 500 uL of RNA Collection Buffer 1 (CBR-1) and 300 uL of nuclease-free water in examples of Steps S110 and S120.”) • U.S. Patent No. 9,540,636 at col. 14:22-28 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 500 uL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 14:48-54 (“In the second example, 500 uL of M4 transport media containing a nasal Swab (donor) was spiked with 2 L of either a 10 dilution (high) or a 10' (low) dilution of EV RNA (purified from 200 uL viral particle lysate and eluted in 20 u, total volume) and then mixed with 500 uL of RNA Collection Buffer 1 (CBR-1) and 0.4 mg of Proteinase K in examples of Steps S110 and S120.”) • U.S. Patent No. 9,540,636 at col. 14:57-63 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 250 uL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 15:22-28 (“In the third example, 500 uL of UTM transport media containing a nasal swab (donor) was spiked with 2 ul of a 10" dilution of EV RNA (purified from 200 uL viral particle lysate and eluted in 20 uL total volume) and then mixed with 500 uL of RNA Collection Buffer 1 (CBR-1) and 0.6 mg of Proteinase K in examples of Steps S110 and S120.”) • U.S. Patent No. 9,540,636 at col. 15:31-36 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x)

Claim	Claim Language	Infringement Evidence
		<p>with 100 uL or 250 uL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 15:60-65 (“In the fourth example, 500 uL of M4 transport media containing a nasal Swab (donor) was spiked with 2 LL of ten-fold dilutions of EV viral particle lysate and then mixed with 500 uL of RNA Collection Buffer 1 (CBR-1) and 0.4 mg of Proteinase K in examples of Steps S110 and S120.”) • U.S. Patent No. 9,540,636 at col. 15:67-16:6 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 16:48-51 (“In the fifth example, 500 uL of Urine or Plasma was spiked with 10pg of GBS DNA and then mixed with 500 uL of DNA Collection Buffer 2 (CBD-2) in examples of Steps S110 and S120.”) • U.S. Patent No. 9,540,636 at col. 16:58-64 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-1 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 17:23-26 (“In the sixth example, 500 uL of Urine (obtained from donor) was spiked with 10 pg of GBS DNA and then mixed with 500 uL of DNA Collection Buffer 2 (CBD-2) in examples of Steps S110 and S120.”) • U.S. Patent No. 9,540,636 at col. 17:29-34 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 17:60-63 (“In the seventh example, 500 uL of Plasma was spiked with 10 pg of GBS DNA and then mixed with 500 uL of DNA Collection Buffer 2 (CBD-2) in examples of Steps S110 and S120.”) • U.S. Patent No. 9,540,636 at col. 17:66-18:5 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL

Claim	Claim Language	Infringement Evidence
		<p>of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the magnetic microparticles to 85 C for 3 minutes in an example of Step S160.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,540,636 at col. 18:31-37 (“In the eighth example, a buccal Swab (obtained from a donor) was added to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg. Proteinase K and then spiked with 10 pg of GBS DNA in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37 C in an example of Step S130.”) U.S. Patent No. 9,540,636 at col. 30:45-47 (“CBD-1 (SP1: ultrapure water (93.1 mL), 1 M Tris pH 7.0 (50 mL), sodium citrate (5.88 g), boric acid (1.24 g), 0.5M EDTA pH 8.0 (2 mL), and Triton-X 100 (10 mL).”) U.S. Patent No. 9,540,636 at col. 18:37-43 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”)U.S. Patent No. 9,540,636 at col. 19:2-13 (“In the ninth example 500 uL of M4 Transport Media (M4) or Universal Transport Media (UTM) containing a buccal Swab (obtained from a donor) was spiked with 10 pg of GBS DNA and then mixed with 500 uL of DNA Collection Buffer 3 (CBD-3) and 0.4 mg of Proteinase K in examples of Steps S110 and S120. For comparison, “Dry Swab’ samples were prepared by adding a buccal swab to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg. Proteinase K and then spiked with 10 pg of GBS DNA. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37 C in an example of Step S130.”) U.S. Patent No. 9,540,636 at col. 19:13-19 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”)U.S. Patent No. 9,540,636 at col. 19:44-50 (“In the tenth example, 100 uL whole blood (donor, obtained from Bioreclamation, Inc.) was added to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg. Proteinase K and then spiked with 10 pg of GBS DNA in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37 C in an example of Step

Claim	Claim Language	Infringement Evidence
		<p>S130.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col.19:51-57 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed twice with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 20:30-37 (“In the eleventh example, 500 uL of urine (obtained from a donor) was spiked with ten-fold serial dilutions of GBS DNA from 1 ng to 10 fg and then mixed with 500 uL of DNA Collection Buffer 2 (CBR-2) in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature in an example of Step S130.”) • U.S. Patent No. 9,540,636 at col. 20:37-43 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 21:2-9 (“In the twelfth example, 500 u, of plasma was spiked with ten-fold serial dilutions of GBS DNA from 1 ng to 10 fg. and then mixed with 500 uL of DNA Collection Buffer 2 (CBR-2) in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature in an example of Step S130.”) • U.S. Patent No. 9,540,636 at col. 21:9-14 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 21:36-42 (“In the thirteenth example, 500 uL of Plasma was spiked with 10 pg of GBS DNA and then mixed with 500 uL of DNA Collection Buffer 2 (CBD-2) in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 0. 2, 5, or 10 minutes at room temperature in examples of Step S130.”) • U.S. Patent No. 9,540,636 at col. 21:43-48 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the

Claim	Claim Language	Infringement Evidence
		<p>affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 21:66-22:5 (“In the fourteenth example, 500 uL of Plasma was spiked with 10pg of GBS DNA and then mixed with 500 uL of DNA Collection Buffer 2 (CBD-2) in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature, 37 C, 45C, or 60 C in examples of Steps S130.”) • U.S. Patent No. 9,540,636 at col. 22:5-11 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at 30:56-57 (“WASH SOLUTION [WSH-1]: ultrapure water (999 mL) and IM Tris pH 8.0 (1 mL).”)U.S. Patent No. 9,540,636 at col. 22:60-67 (“In the fifteenth example, 500 uL of Urine (obtained from a donor) was spiked with 10 pg of GBS DNA and then mixed with 500 uL of DNA Collection Buffer 2 (CBD-2) in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature, 37 C, 45 C, or 60 C in examples of Step S130.”) • U.S. Patent No. 9,540,636 at col. 24:16-22 (“In the seventeenth example, 500 uL of M4 was spiked with ten-fold serial dilutions of 1 uL of EV viral particle lysate and 1 LL of GBS DNA and then mixed with 500 uL of RNA Collection Buffer 3 (CBR-3) in examples of Steps S110 and S120. RNA and DNA were allowed to bind to the PAA affinity moieties for 10 minutes at 37C in an example of Step S130.”) • U.S. Patent No. 9,540,636 at col. 30:35-38 (“CBR-1 2xTCEP Buffer Formulation: ultrapure water (94.6 mL), 1 M Tris pH 7.0 (20 mL), Tris(2-carboxyethyl) phosphine hydrochloride, or TCEP (14.3 g), and Triton-X 100 (20 mL).”) • U.S. Patent No. 9,540,636 at col. 30:48-50 (“CBD-2 SP2: ultrapure water (480 mL), 1 M Tris pH 7.0 (100 mL), sodium citrate (11.76 g), boric acid (2.48 g), 0.5M EDTA pH 8.0 (400 mL), and Triton-X 100 (20 mL).”) • U.S. Patent No. 9,540,636 at col. 30:51-53 (“CBD-3 ISP3: ultrapure water (862 mL), 1 M Tris pH 7.0 (100 mL), sodium citrate (11.76 g), boric acid (2.48 g), 0.5M EDTA pH 8.0 (4 mL), and Triton-X 100 (20 mL).”)

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> U.S. Patent No. 9,540,636 at 30:56-57 (“WASH SOLUTION [WSH-1]: ultrapure water (999 mL) and IM Tris pH 8.0 (1 mL).”) <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10. Claim 4. The method of claim 3, wherein incubating the moiety-sample mixture comprises heating the moiety-sample solution to a temperature in the range of 25-95° C. for 5-60 minutes, thus simultaneously lysing the biological sample and facilitating binding of nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles. Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety

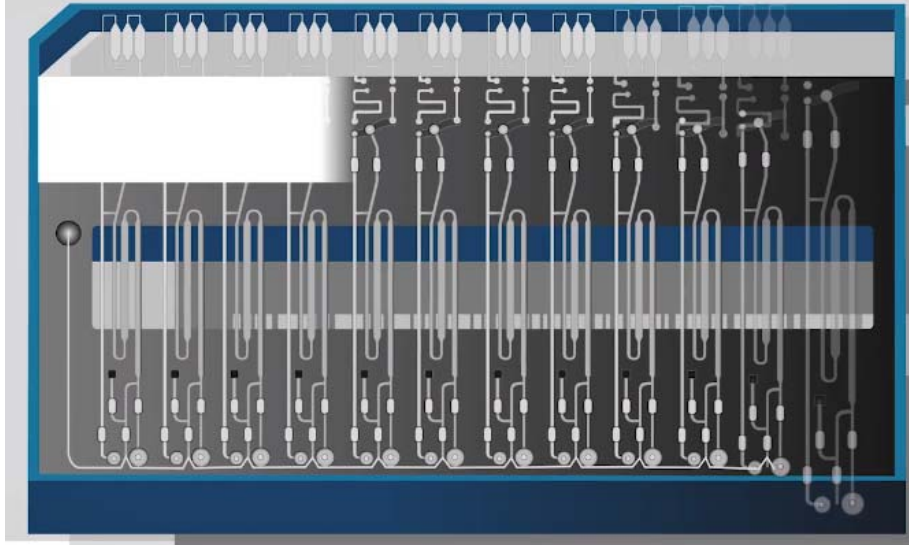
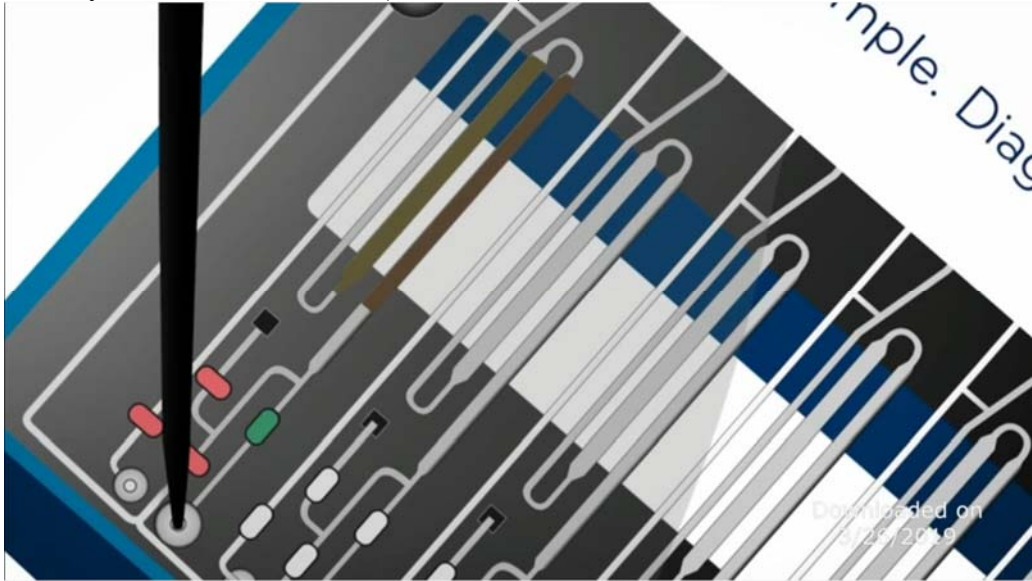
Claim	Claim Language	Infringement Evidence
		<p>solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the microfluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20 uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction.</p> <ul style="list-style-type: none"> • Claim 19. A method for nucleic acid isolation from a biological sample, comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution includes a set of affinity moiety-coated microparticles, comprising a set of microparticles amide-bonded to at least one of poly(allylamine) of molecular weight <30,000 Da and Polypropylenimine tetramine dendrimer Generation 1; producing a moiety-sample mixture upon combination of the binding moiety solution with the biological sample; producing a set of moiety-bound nucleic acid particles upon incubation of the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of the set of pins includes reversing displacement of at least one pin of the first subset of the set of pins, and reversing occlusion of a portion of the fluidic pathway. • U.S. Patent No. 9,382,532 at col. 3:35-43 (“The method 100 can be performed in any container or

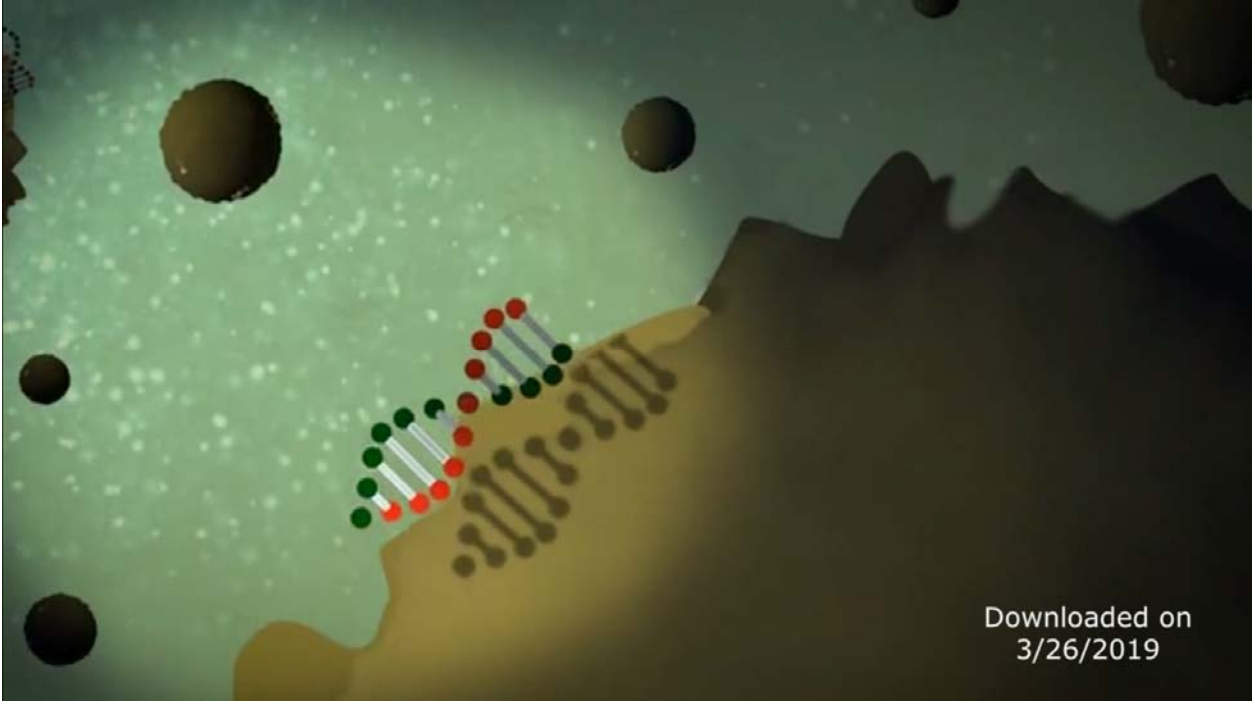
Claim	Claim Language	Infringement Evidence
		<p>process chamber that is configured to contain a suitable concentration of affinity moiety-coated microparticles, facilitate suitable buffer conditions to allow for binding (e.g., buffer conditions providing a suitably low pH), contain suitable amounts of proteolytic or other enzymes for effective lysis or removal of inhibitory substances, and provide suitable thermal conditions that collectively enable binding of nucleic acids to the affinity moiety-coated microparticles.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at 4:56-60 (“Step S120 recites mixing the binding moiety solution with a biological sample, within the process chamber, in order to produce a moiety-sample solution, which functions to initiate lysis of the biological sample and enable target nucleic acids to bind to affinity moieties of the binding moiety solution.”) • U.S. Patent No. 9,382,532 at 5:3-7 (“In Step S120, the process chamber can be any suitable vessel, as shown in FIG. 1A, or a suitable capture plate, such as that described in U.S. patent application Ser. No. 13/766,359, entitled “System and Method for Processing and Detecting Nucleic Acids”, as shown in FIG. 1B.”) • U.S. Patent No. 9,382,532 at 5:47-61 (“In Step S130, the moiety-sample solution can be incubated using any suitable heating apparatus, as shown in FIG. 1A, or a suitable capture plate heater, such as that described in U.S. patent application Ser. No. 13/766,359, entitled "System and Method for Processing and Detecting Nucleic Acids", as shown in FIG. 1B. In Step S130, the nucleic acid is released from within the cell or other structure that it is contained within, and binds to the microparticles coupled with the affinity moiety, while other unbound components form a waste volume for later removal, as shown in FIG. 1 C. Preferably, the process chamber containing the moiety-sample solution (e.g., lysis, clean-up, binding reagents and the biological sample) is incubated for a defined period of time at a temperature preferably in the range of 25-95 C, wherein time and temperature parameters are biological sample-dependent.”) • U.S. Patent No. 9,382,532 at 17:31-37 (“In the eighth example, a buccal Swab (obtained from a donor) was added to 1 mL of DNA Collection Buffer 1 (CBD 1) containing 0.4 mg. Proteinase K and then spiked with 10 pg of GBS DNA in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37C in an example of Step S130.”) • U.S. Patent No. 9,382,532 at col. 28:49-51 (“CBD-1 (SP1: ultrapure water (93.1 mL), 1 M Tris pH 7.0 (50 mL), sodium citrate (50.88 g), boric acid (1.24 g), 0.5M EDTA pH 8.0 (2 mL), and

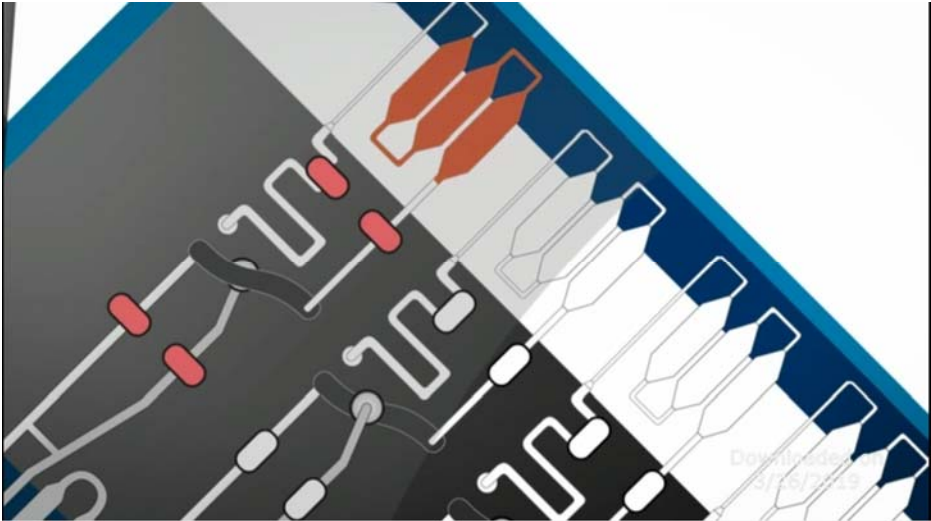
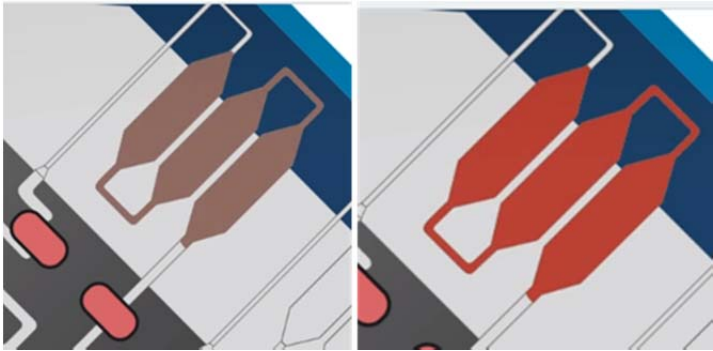
Claim	Claim Language	Infringement Evidence
		<p>Triton-X 100 (10 mL).”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at col. 17:64-18:8 (“In the ninth example 500 uL of M4 Transport Media (M4) or Universal Transport Media (UTM) containing a buccal Swab (obtained from a donor) was spiked with 10pg of GBS DNA and then mixed with 500 uL of DNA Collection Buffer 3 (CBD-3) and 0.4 mg of Proteinase K in examples of Steps S110 and S120. For comparison, “Dry Swab’ samples were prepared by adding a buccal swab to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg Proteinase K and then spiked with 10 pg of GBS DNA. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37C in an example of Step S130.”) • U.S. Patent No. 9,382,532 at col. 28:55-57 (“CBD-3 ISP3: ultrapure water (862 mL), 1 M Tris pH 7.0 (100 mL), sodium citrate (11.76 g), boric acid (2.48 g), 0.5M EDTA pH 8.0 (4 mL), and Triton-X 100 (20 mL).”) • U.S. Patent 9,382,532 at col. 18:34-41 (“In the tenth example, 100 uL whole blood (donor, obtained from Bioreclamation, Inc.) was added to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg. Proteinase K and then spiked with 10pg of GBS DNA in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37 C in an example of Step S130.”) • U.S. Patent No. 9,382,532 at col. 21:27-33 (“In the fifteenth example, 500 uL of Urine (obtained from a donor) was spiked with mpg of GBS DNA and then mixed with 500 uL of DNA Collection Buffer 2 (CBD-2) in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature, 37 C, 45C, or 60 C in examples of Step S130.”) • U.S. Patent No. 9,382,532 at col. 28:52-54 (“CBD-2 SP2: ultrapure water (480 mL), 1 M Tris pH 7.0 (100 mL), sodium citrate (11.76 g), boric acid (2.48 g), 0.5M EDTA pH 8.0 (400 mL), and Triton-X 100 (20 mL).”) • U.S. Patent No. 9,382,532 at col. 22:37-43 (“In the seventeenth example, 500 uL of M4 was spiked with ten-fold serial dilutions of 1 uL of EV viral particle lysate and 1 uL of GBSDNA and then mixed with 500 uL of RNA Collection Buffer 3 (CBR-3) in examples of Steps S110 and S120. RNA and DNA were allowed to bind to the PAA affinity moieties for 10 minutes at 37 C in an example of Step S130.”) • U.S. Patent No. 9,382,532 at col. 28:46-48 (“CBR-3 2x EDTA only Buffer: ultrapure water (560 mL), 1M Tris pH 8.0 (20 mL), 0.5M EDTA pH 8.0 (400 mL), and Triton-X 100 (20 mL).”)

Claim	Claim Language	Infringement Evidence
		<p>US9604213 (Exhibit 30)</p> <ul style="list-style-type: none"> • Claim 1: A system for processing and detecting nucleic acids in cooperation with a cartridge comprising a heating region defined at a first surface, and a magnet housing region defined at a second surface in thermal communication with the first surface, the system comprising: a capture plate configured to facilitate combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate and separate nucleic acids from the set of magnetic beads, comprising: a cartridge platform configured to receive the cartridge and comprising a magnet receiving slot aligned with the second surface during operation, a heater configured to transmit heat to the heating region at the first surface during operation, and a magnet coupled to a magnet heating element that heats the magnet during operation with the magnet proximal the second surface, the magnet configured to pass through the magnet receiving slot into the magnet housing region during operation, thereby facilitating separation of a nucleic acid volume from the magnetic bead-sample and heating of the magnetic bead-sample in cooperation with the heater. • U.S. Patent No. 9,604,213 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling Subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation Subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical Subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay Strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) • U.S. Patent No. 9,604,213 at col. 3:62-66 (“As shown in FIGS. 3A and 3B, the capture plate 110 comprises a capture plate substrate in comprising a set of wells 112 and a puncturable foil seal 115, and functions to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119.”) • U.S. Patent No. 9,604,213 at col. 4:23-33 (“The set of wells 112 of the capture plate substrate

Claim	Claim Language	Infringement Evidence
		<p>in function to receive at least one biological sample which contain or are suspected of potentially containing nucleic acids, and to facilitate combination of the biological sample with a set of magnetic beads 119.”)</p> <p>US1001888 (Exhibit 55)</p> <ul style="list-style-type: none"> Claim 14: A method for processing and detecting nucleic acids from a sample with a cartridge including a fluidic pathway passing between a heating region of the cartridge and a magnet housing region of the cartridge, wherein the method comprises: with a liquid handling system, combining the sample with a quantity of magnetic beads to produce a nucleic acid-magnetic bead sample; with the liquid handling system, transferring the nucleic acid-magnetic bead sample to the fluidic pathway of the cartridge; and contemporaneously transmitting heat through the heating region, by way of a heater, and transmitting heat through the magnet housing region, by way of a magnet heating element coupled to a magnet, thereby facilitating capture of nucleic acids of the sample at the fluidic pathway of the cartridge. U.S. Patent 10,010,888 at col. 4:29-39 (“The set of wells 112 of the capture plate substrate 111 function to receive at least one biological sample which contain or are suspected of potentially containing nucleic acids, and to facilitate combination of the biological sample with a set of magnetic beads 119.”)
1(j)	a first heat source and a second heat source located external to the microfluidic network	<p>The accused system comprises a first heat source and a second heat source located external to the microfluidic network.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMoDx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59

Claim	Claim Language	Infringement Evidence
		 <p>2:28 Lysate in the S-channel (extraction)</p> 

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber. A precise volume of air is then applied to remove any remaining liquid into the waste chamber. NeuMoDx wash solution is pumped via the fluid port into the microfluidic cartridge to remove all unbound material, followed by another volume of air to remove excess wash solution. High pH NeuMoDx release reagent is dispensed into the s-channel to cover the beads, and heat is applied to the denaturation process, resulting in released nucleic acid or eluate.” <i>Id.</i> at 2:28-3:12. • 3:04 Heat/denaturation  <p>Downloaded on 3/26/2019</p> <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins. During a series of independent heat on-heat off sequences, an optical scanner measures the level of fluorescence

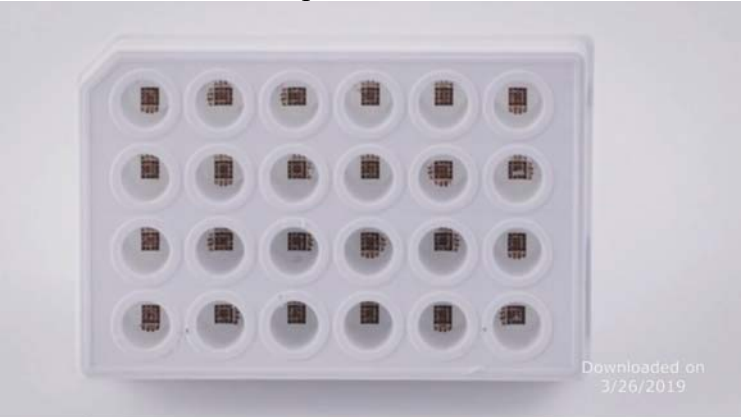

Claim	Claim Language	Infringement Evidence
		<p>emitted, and converts it into the qualitative or quantitative results which are displayed as amplification curves for analysis by the laboratorian.” <i>Id.</i> at 3:58-4:26</p> <ul style="list-style-type: none"> • 4:08 PCR chambers   <p>On information and belief, the accused system comprises a first heat source and a second heat source located external to the microfluidic network.</p>

Claim	Claim Language	Infringement Evidence
		<p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 5. The system of claim 1, further comprising a capture plate module comprising a thermally conducting substrate configured to cradle at least one well of the capture plate, and a heater coupled to the thermally conducting substrate. • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at 9:4-21 (“The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210... The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR).”) • U.S. Patent No. 9,050,594 at 10:49-55 (“The cartridge heater 153 functions to transfer heat to a heating region 224 of a microfluidic cartridge 210, for inducing a pH shift to release bound nucleic acids from magnetic beads within the heating region 224. The cartridge heater 153 is preferably a plate-shaped heater configured to transfer heat to the microfluidic cartridge 210 only from one side of the cartridge heater 153, such that heat flows through one face of the plate-shaped heater to the microfluidic cartridge 210.”) • U.S. Patent No. 9,050,594 at col. 10:29-48 (“The heating and cooling subsystem 150 of the molecular diagnostic module 130 comprises a cartridge heater 153, a fan 155, and a set of detection chamber heaters 157 and functions to controllably heat portions of a microfluidic cartridge 210 for processing of a biological sample containing nucleic acids according to a molecular diagnostic protocol.”) • U.S. Patent No. 9,050,594 at 11:56-58 (“The set of detection chamber heaters 157 functions to individually heat detection chambers of a set of detection chambers 213 within a microfluidic cartridge 210.”)

Claim	Claim Language	Infringement Evidence
		<p>US9499896 (Exhibit 28)</p> <ul style="list-style-type: none"> • Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising: an assembly including a first insulating layer, a heating region comprising an adhesion material layer coupled to the first insulating layer and a noble material layer coupled to the adhesion material layer, and a second insulating layer coupled to the heating region and to the first insulating layer through a pattern of voids in the heating region, wherein the pattern of voids in the heating region defines a coarse pattern, comprising a global morphology at a first scale and associated with a heating element of the heating region, and a fine pattern, comprising a local morphology at a second scale smaller than the first scale, integrated into the coarse pattern and associated with a sensing element of the heating region; an electronics substrate configured to couple heating elements and sensing elements of the set of heater-sensor dies to a controller; and a set of elastic elements coupled to a second substrate surface of the electronics substrate opposing a first substrate surface of the electronics substrate interfacing with the assemblies of the set of heater-sensor dies and configured to bias each of the set of heater-sensor dies against a detection chamber in a configuration wherein the set of heater-sensor dies is in thermal communication with a set of detection chambers. • U.S. Patent No. 9,499,896 at 2:33-48 “The system 100 functions to enable rapid thermal cycling of samples while providing uniform heating and preventing signal drift. In specific applications, the system 100 can be used to rapidly and controllably thermocycle nucleic acid samples during performance of molecular diagnostic amplification techniques (e.g., PCR, RT-PCR), signal amplification techniques (e.g., bDNA, hybrid capture), and analytical techniques (e.g., gel electrophoresis, mass spectrometry). The system 100 can also provide rapid thermocycling without significant power requirements, ensure a closer correlation between the actual heating temperature and the temperature set-point by implementing an integrated heater-sensor die, and controllably and individually heat small sample volumes (e.g., picoliters, nanoliters) based upon a microfabrication technique that also enables mass production of the system 100.”) • U.S. Patent No. 9,499,896 at 12:15-20 (“Furthermore, the controller 165 can be configured to control individual heater-sensor dies 111 in order to provide unique heating parameters for individual detection chambers and/or can be configured to provide common heating parameters for all heater-sensor dies 111 in the set of heater-sensor dies 110.”)

Claim	Claim Language	Infringement Evidence
		<p>US9539576 (Exhibit 29)</p> <ul style="list-style-type: none"> • Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising a heating surface configured to interface with a detection chamber and an inferior surface, inferior to the heating surface, including a connection point, wherein each of the set of heater-sensor dies includes a heating element and a sensing element; an electronics substrate, comprising a first substrate surface coupled to the inferior surface of each of the set of heater-sensor dies, a set of apertures longitudinally spaced across the electronics substrate and providing access through the electronics substrate to the set of heater-sensor dies, and a second substrate surface inferior to the first substrate surface, wherein the electronics substrate comprises a set of substrate connection points at least at one of the first substrate surface, an aperture surface defined within at least one of the set of apertures, and the second substrate surface, and wherein the electronics substrate couples the heating element and the sensing element of each of the set of heater-sensor dies to a controller; a set of heat-sink supports coupled to at least one of 1) the set of heater-sensor dies, through the set of apertures, and 2) the second substrate surface of the electronics substrate and configured to dissipate heat generated by the set of heater-sensor dies, wherein at least one of the set of heat-sink supports includes an integrated cooling element, and wherein a base surface of each of the set of heat-sink supports is coupled to an elastic element that transmits a biasing force through the electronics substrate, thereby maintaining thermal communication between the set of heater-sensor dies and a set of detection chambers upon alignment of the set of heater-sensor dies with the set of detection chambers; and a set of wire bonds, including a wire bond coupled between the connection point of at least one of the set of heater-sensor dies and one of the set of substrate connection points. • U.S. Patent No. 9,539,576 at 9:8-12 (“Furthermore, the controller 165 can be configured to control individual heater-sensor dies 111 in order to provide unique heating parameters for individual detection chambers and/or can be configured to provide common heating parameters for all heater-sensor dies 111 in the set of heater-sensor dies no.”) • U.S. Patent No. 9,539,576 at 12:59-64 (“Upon completion of Block S240, individual heater-sensor dies of the set of heater-sensor dies can be coupled to one or multiple electronics substrates in order to provide uniform heating of individual sample containers with independent

Claim	Claim Language	Infringement Evidence
		<p>control of heating parameters provided at each of the set of heater-sensor dies.”)</p> <p>US9441219 (Exhibit 53)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,441,219 at col. 3:35-54 (“A heating and cooling subsystem 150, a magnet 160, and a valve actuation subsystem 170 of the molecular diagnostic module 130 then facilitate separation of a set of nucleic acids from the magnetic bead-samples, as the liquid handling system 250 dispenses wash solutions, release solutions, and/or air at appropriate stages. The liquid handling system 250 then aspirates the set of nucleic acids from the micro-fluidic cartridge 210 contained within the molecular diagnostic module 130, combines the set of nucleic acids with a set of molecular diagnostic reagents using an assay strip 190, and dispenses the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the microfluidic cartridge 210 within the molecular diagnostic module 130. The detection chamber heaters 157, optical subsystem 180 and valve actuation subsystem 170 of the molecular diagnostic module 130 then facilitate analysis of the set of nucleic acid-reagent mixtures by a processor configured to display information on a user interface.”) U.S. Patent No. 9,441,219 at col. 10:45-51 (“The heating and cooling subsystem 150 of the molecular diagnostic module 130 comprises a cartridge heater 153, a fan 155, and a set of detection chamber heaters 157 and functions to controllably heat portions of a microfluidic cartridge 210 for processing of a biological sample containing nucleic acids according to a molecular diagnostic protocol.”) <p>US9339812 (Exhibit 26)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,339,812 at col. 10:29-43 (“The heating and cooling subsystem 150 of the molecular diagnostic module 130 comprises a cartridge heater 153, a fan 155, and a set of detection chamber heaters 157 and functions to controllably heat portions of a microfluidic cartridge 210 for processing of a biological sample containing nucleic acids according to a molecular diagnostic protocol.”)
1(k)	a lysing heater configured to apply heat to the lysate solution and the plurality of magnetic binding particles in the lysing	<p>The accused system comprises a lysing heater configured to apply heat to the lysate solution and the plurality of magnetic binding particles in the lysing container wherein the lysing heater is separate and distinct from the first and second heat sources.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM),</p>

Claim	Claim Language	Infringement Evidence
	<p>container wherein the lysing heater is separate and distinct from the first and second heat sources</p>	<p>http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> 0:40 Extraction plate  <p>1:03 liquid handling robot</p>  <ul style="list-style-type: none"> “Each extraction plate well is then heated independently for 10 minutes to ensure proper lysing and binding of the nucleic acids to the paramagnetic beads. The temperatures applied range from 37 degrees Celsius to 60 degrees Celsius, resulting in the flexibility to process a wide

Claim	Claim Language	Infringement Evidence
		<p>variety of DNA and RNA IVD and LDT tests simultaneously.” <i>Id.</i> at 1:05.</p> <p>40600106_ Rev-D-IFU-NeuMoDx-Lysis-Buffer-1-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 63)</p> <ul style="list-style-type: none"> The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/removal of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with NeuMoDx Lysis Buffer 1 and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. NeuMoDx Lysis Buffer 1 is especially formulated and optimized for extraction of bacterial or viral DNA in plasma and serum samples, by providing an optimal environment for cell/particle lysis and DNA binding to occur. The stringent formulation of the buffer also inhibits or reduces any nuclease activity present in the sample thereby protecting the viral or bacterial DNA from degradation. <p>40600105_ Rev-D-IFU-NeuMoDx-Lysis-Buffer-2-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 64)</p> <ul style="list-style-type: none"> The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/removal of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed urine specimen is mixed with NeuMoDx Lysis Buffer 2 and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. NeuMoDx Lysis Buffer 2 is especially formulated and optimized for extraction of bacterial DNA from human urine samples, by providing an optimal environment for cell/particle lysis and DNA binding to occur. The stringent formulation of the buffer also inhibits or reduces any nuclease activity present in the sample thereby protecting the bacterial DNA from degradation. <p>40600104_ Rev-D-IFU-NeuMoDx-Lysis-Buffer-3-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 65)</p> <ul style="list-style-type: none"> The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/removal of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic

Claim	Claim Language	Infringement Evidence
		<p>acid for detection by Real-Time PCR. An aliquot of unprocessed specimen is mixed with NeuMoDx Lysis Buffer 3 and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. NeuMoDx Lysis Buffer 3 is especially formulated and optimized for extraction of viral RNA from human plasma and serum samples by providing an optimal environment for cell/particle lysis and nucleic acid binding to occur. The stringent formulation of the buffer also inhibits or reduces any nuclease activity present in the sample thereby protecting the viral RNA from degradation.</p> <p>40600103_Rev-D-IFU-NeuMoDx-Lysis-Buffer-4-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 66)</p> <ul style="list-style-type: none"> The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of enriched Lim Broth is mixed with NeuMoDx Lysis Buffer 4 and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres dried in the NeuMoDx Extraction Plate. <p>40600100_Rev-D-IFU-NeuMoDx-WASH-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 58)</p> <ul style="list-style-type: none"> The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. <p>40500098_D-IFU-NeuMoDx-Extraction-Plate-US-ONLY (Exhibit 59)</p> <ul style="list-style-type: none"> “Each 24-well NeuMoDx Extraction Plate contains dried, room-temperature stable reagents including proprietary coated magnetic microspheres, a lytic enzyme, and RNA and DNA Sample Process Controls. Components within the extraction plate work in conjunction with the appropriate NeuMoDx lysis buffer to lyse cells in a temperature dependent manner and bind the nucleic acid while reducing activity of any nucleases

Claim	Claim Language	Infringement Evidence
		<p>present in clinical samples. The Sample Process Controls bind to the magnetic microspheres at the same time as the target nucleic acid, and are carried throughout the extraction procedure, serving as internal controls to monitor for any inefficiencies in the extraction process and presence of PCR interference substances.” <i>Id.</i> at 1.</p> <ul style="list-style-type: none"> • “The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate lysis buffer in the NeuMoDx Extraction Plate and is subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres.” <i>Id.</i> at 1. <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> • “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System... The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.” <p>US9540636 (Exhibit 54)</p> <ul style="list-style-type: none"> • Claim 6. The method of claim 3, wherein incubating the moiety-sample mixture comprises heating the moiety-sample solution to a temperature above 25° C for at least 5 minutes, thus simultaneously lysing the biological sample and facilitating binding of nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles. • U.S. Patent No. 9,540,646 at col. 6:2-9 (“Preferably, the process chamber containing the moiety-sample solution (e.g., lysis, clean-up, binding reagents and the biological sample) is incubated for a defined period of time at a temperature preferably in the range of 25-95 C, wherein time and temperature parameters are biological sample-dependent. Example parameters for different biological samples are described briefly

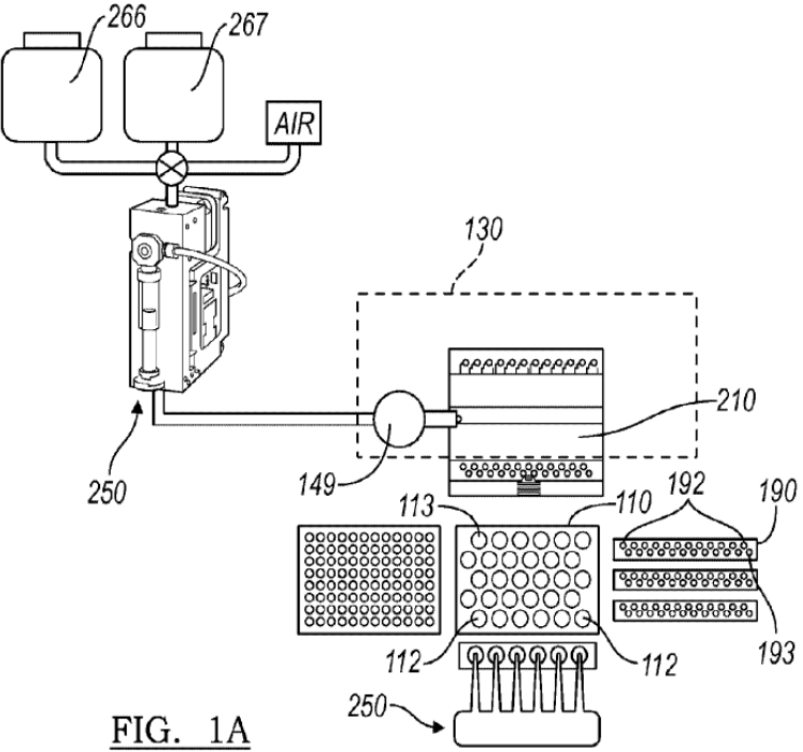
Claim	Claim Language	Infringement Evidence
		<p>below, and further in Section 3 below.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,646 at col. 6:24-31 (“In a variation of the first example, enteroviral particles treated with Proteinase K can be incubated and lysed within a modified temperature range of 37-60C for optimal activity of the proteinase enzyme. In a second example of Step S130, a nasal Swab containing Staphylococcus aureus bacteria is incubated at approximately 95 C to ensure thorough lysis of the gram-positive bacteria.”) • U.S. Patent No. 9,540,636 at col. 14:19-22 (“In an example of Step S130, RNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 60 C.”) • U.S. Patent No. 9,540,636 at col. 14:48-56 (“In the second example, 500 uL of M4 transport media containing a nasal Swab (donor) was spiked with 2 L of either a 10 dilution (high) or a 10'(low) dilution of EV RNA (purified from 200 uL viral particle lysate and eluted in 20 u, total volume) and then mixed with 500 uL of RNA Collection Buffer 1 (CBR-1) and 0.4 mg of Proteinase K in examples of Steps S110 and S120. RNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 60 C. in an example of Step S130.”) • U.S. Patent No. 9,540,636 at col. 15:22-30 (“In the third example, 500 uL of UTM transport media containing a nasal swab (donor) was spiked with 2 ul of a 10" dilution of EV RNA (purified from 200 uL viral particle lysate and eluted in 20 uL total volume) and then mixed with 500 uL of RNA Collection Buffer 1 (CBR-1) and 0.6 mg of Proteinase K in examples of Steps S110 and S120. RNA was allowed to bind to the PAA affinity particles coated onto magnetic microparticles for 10 minutes at 60 C. in an example of Step S130.”) • U.S. Patent No. 9,540,636 at col. 15:60-67 (“In the fourth example, 500 uL of M4 transport media containing a nasal Swab (donor) was spiked with 2 LL of ten-fold dilutions of EV viral particle lysate and then mixed with 500 uL of RNA Collection Buffer 1 (CBR-1) and 0.4 mg of Proteinase K in examples of Steps S110 and S120. RNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 60 C. in an example of Step S130.”) • U.S. Patent No. 9,540,636 at col. 16:48-58 (“In the fifth example, 500 u, of Urine or Plasma was spiked with 10pg of GBS DNA and then mixed with 500 uL of DNA

Claim	Claim Language	Infringement Evidence
		<p>Collection Buffer 2 (CBD-2) in examples of Steps S110 and S120. Alternately, a buccal swab was added to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg. Proteinase K and then spiked with 10 pg of GBS DNA in other examples of Steps S110 and S120. DNA was allowed to bind to the DABAM affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature or 60 C depending on matrix used in examples of Step S130.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 18:31-37 (“In the eighth example, a buccal Swab (obtained from a donor) was added to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg. Proteinase K and then spiked with 10 pg of GBS DNA in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37 C in an example of Step S130.”) • U.S. Patent No. 9,540,636 at col. 19:2-13 (“In the ninth example 500 uL of M4 Transport Media (M4) or Universal Transport Media (UTM) containing a buccal Swab (obtained from a donor) was spiked with 10 pg of GBS DNA and then mixed with 500 uL of DNA Collection Buffer 3 (CBD-3) and 0.4 mg of Proteinase K in examples of Steps S110 and S120. For comparison, “Dry Swab’ samples were prepared by adding a buccal swab to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg. Proteinase K and then spiked with 10 pg of GBS DNA. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37 C in an example of Step S130.”) • U.S. Patent No. 9,540,636 at col. 19:44-50 (“In the tenth example, 100 uL whole blood (donor, obtained from Bioreclamation, Inc.) was added to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg. Proteinase K and then spiked with 10 pg of GBS DNA in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microp articles for 10 minutes at 37 C in an example of Step S130.”) • U.S. Patent No. 9,540,636 at col. 22:60-67 (“In the fifteenth example, 500 uL of Urine (obtained from a donor) was spiked with 10 pg of GBS DNA and then mixed with 500 uL of DNA Collection Buffer 2 (CBD-2) in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature, 37 C, 45 C, or 60 C in examples of Step S130.”) • U.S. Patent No. 9,540,636 at col. 24:16-22 (“In the seventeenth example, 500 uL of M4


Claim	Claim Language	Infringement Evidence
		<p>was spiked with ten-fold serial dilutions of 1 uL of EV viral particle lysate and 1 LL of GBS DNA and then mixed with 500 uL of RNA Collection Buffer 3 (CBR-3) in examples of Steps S110 and S120. RNA and DNA were allowed to bind to the PAA affinity moieties for 10 minutes at 37C in an example of Step S130.”)</p> <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 (“Preferably, the process chamber containing the moiety-sample solution (e.g., lysis, clean-up, binding reagents and the biological sample) is incubated for a defined period of time at a temperature preferably in the range of 25-95 C, wherein time and temperature parameters are biological sample-dependent. Example parameters for different biological samples are described briefly below, and further in Section 3 below.”) • U.S. Patent No. 9,382,532 at col. 6:8-15 (“In a first example of Step S130, enteroviral particles are incubated and lysed at room temperature in the presence of detergent. In a variation of the first example, enteroviral particles treated with Proteinase K can be incubated and lysed within a modified temperature range of 37-60C for optimal activity of the proteinase enzyme.”) • U.S. Patent. No. 9,382,532 at col. 6:15-21 (“In a second example of Step S130, a nasal Swab containing Staphylococcus aureus bacteria is incubated at approximately 95 C to ensure thorough lysis of the gram positive bacteria. In variations of the second example, treatment of the bacterial sample with specific lytic enzymes (e.g., achromopeptidase or lysostaphin) can result in modified lysis temperature.”) • U.S. Patent No. 9,382,532 at col. 13:45-55 (“In the first example, 200LL of CSF was spiked with 2 ul of EV viral particle lysate and then mixed with 500LL of RNA Collection Buffer 1 (CBR-1) and 300 uL of nuclease-free water in examples of Steps S110 and S120. As a comparison, a similar amount of EV particle lysate was spiked into a 1 mL solution comprised of 500LL of CBR-1 buffer and 500LL of nuclease free water and processed simultaneously. In an example of Step S130, RNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 60 C.”) • U.S. Patent No. 9,382,532 at col. 14:9-18 (“In the second example, 500 uL of M4 transport media containing a nasal Swab (donor) was spiked with 2Lofeithera 10 dilution


Claim	Claim Language	Infringement Evidence
		<p>(high) or a 10' (low) dilution of EV RNA (purified from 200 uL viral particle lysate and eluted in 20 u, total volume) and then mixed with 500 uL of RNA Collection Buffer 1 (CBR-1) and 0.4 mg of Proteinase K in examples of Steps S110 and S120. RNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 60C in an example of Step S130.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at 14:45-53 (“In the third example, 500 uL of UTM transport media containing a nasal swab (donor) was spiked with 2 uL of a 10" dilution of EV RNA (purified from 200 uL viral particle lysate and eluted in 20 uL total volume) and then mixed with 500 uL of RNA Collection Buffer 1 (CBR-1) and 0.6 mg of Proteinase K in examples of Steps S110 and S120. RNA was allowed to bind to the PAA affinity particles coated onto magnetic microparticles for 10 minutes at 60 C in an example of Step S130.”) • U.S. Patent No. 9,382,532 at 15:12-19 (“In the fourth example, 500 uL of M4 transport media containing a nasal Swab (donor) was spiked with 2 uL, often-fold dilutions of EV viral particle lysate and then mixed with 500 uL of RNA Collection Buffer 1 (CBR-1) and 0.4 mg of Proteinase K in examples of Steps S110 and S120. RNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 60C in an example of Step S130.”) • U.S. Patent No. 9,382,532 at 16:2-6 (“DNA was allowed to bind to the DABAM affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature or 60 C depending on matrix used in examples of Step S130.”) • U.S. Patent No. 9,382,532 at 17:31-37 (“In the eighth example, a buccal Swab (obtained from a donor) was added to 1 mL of DNA Collection Buffer 1 (CBD 1) containing 0.4 mg. Proteinase K and then spiked with 10 pg of GBS DNA in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37C in an example of Step S130.”) • U.S. Patent No. 9,382,532 at col. 18:5-8 (“DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37C in an example of Step S130.”) • U.S. Patent 9,382,532 at col. 18:34-41 (“In the tenth example, 100 uL whole blood (donor, obtained from Bioreclamation, Inc.) was added to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg. Proteinase K and then spiked with 10pg of GBS DNA in

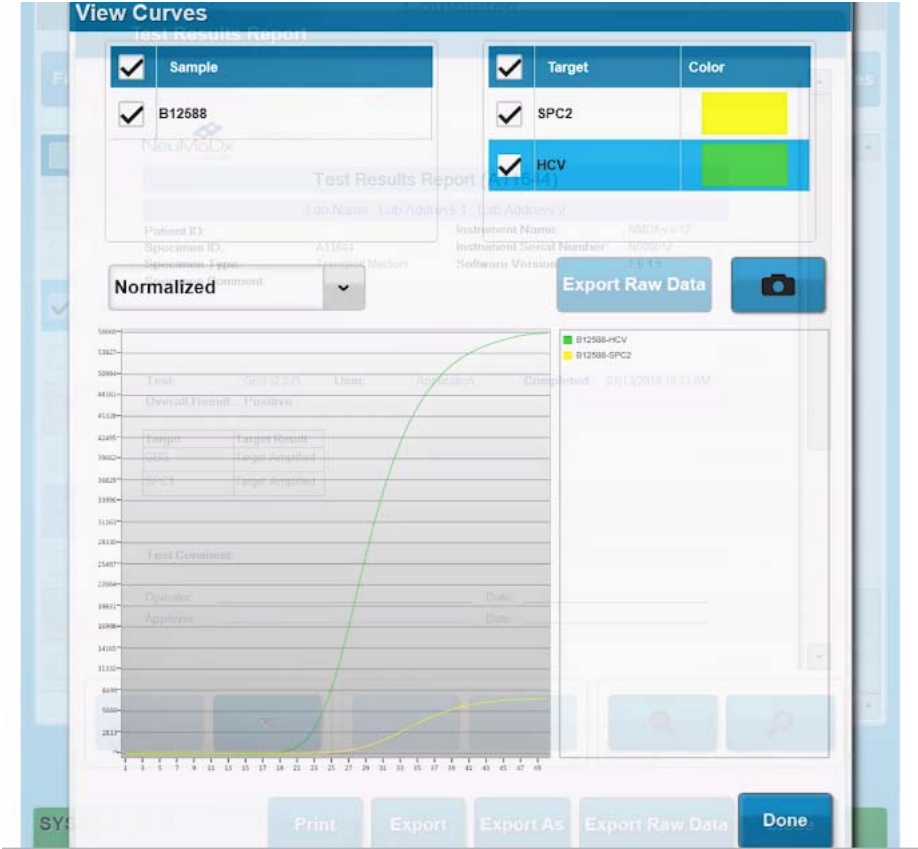
Claim	Claim Language	Infringement Evidence
		<p>examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37 C in an example of Step S130.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,382,532 at 20:38-44 (“In the fourteenth example, 500 uL of Plasma was spiked with mpg of GBS DNA and then mixed with 500 uL of DNA Collection Buffer 2 (CBD-2) in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature, 37 C, 45C, or 60C in examples of Steps S130.”) U.S. Patent No. 9,382,532 at col. 21:27-33 (“In the fifteenth example, 500 uL of Urine (obtained from a donor) was spiked with mpg of GBS DNA and then mixed with 500 uL of DNA Collection Buffer 2 (CBD-2) in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature, 37 C, 45C, or 60 C in examples of Step S130.”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 5. The system of claim 1, further comprising a capture plate module comprising a thermally conducting substrate configured to cradle at least one well of the capture plate, and a heater coupled to the thermally conducting substrate. Claim 12. The system of claim 1, wherein the molecular diagnostic module further comprises a molecular diagnostic module heater configured to heat at least one magnetic bead-sample. Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. U.S. Patent No. 9,050,594 at 2:49-58 (“As shown in FIGS. 1A-1B and 7A, an embodiment of a system 100 for processing and detecting nucleic acids comprises: a capture plate 110 configured to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119; a molecular diagnostic module 130 comprising a microfluidic cartridge receiving module 140, heating and cooling subsystem 150, a magnet 160, a valve actuation subsystem 170, an optical subsystem 180; and an assay

Claim	Claim Language	Infringement Evidence
		<p>strip 190 configured to facilitate mixing of molecular diagnostic reagents with a nucleic acid volume.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at FIG. 1A.  <p style="text-align: center;">FIG. 1A</p>
1(l)	an operating system comprising a processor, the processor configured to actuate the first and	<p>The accused system comprises an operating system comprising a processor, the processor configured to actuate the first and second heat sources and the lysing heater.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May</p>

Claim	Claim Language	Infringement Evidence
	second heat sources and the lysing heater	<p>31, 2019 (Exhibit 11)</p> <p>On information and belief, the accused system comprises an operating system comprising a processor, the processor configured to actuate the first and second heat sources and the lysing heater.</p> <ul style="list-style-type: none"> • “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION. Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieving [sic] optimal operational and clinical performance for our customers and their patients.” • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents. • “The NeuMoDx™ 96 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 288 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 288 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p>

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none">• “The NeuMoDx Molecular N96 and N288 are fully automated sample to result molecular diagnostics platforms. They provide continuous random access processing with initial results in one hour and operator walk away time of up to eight hours.” <i>Id.</i> at 0:00-0:18• 0:40 Extraction plate  <p>Downloaded on 3/26/2019</p> <p>1:03 liquid handling robot</p>

Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none"> • “Each extraction plate well is then heated independently for 10 minutes to ensure proper lysing and binding of the nucleic acids to the paramagnetic beads. The temperatures applied range from 37 degrees Celsius to 60 degrees Celsius, resulting in the flexibility to process a wide variety of DNA and RNA IVD and LDT tests simultaneously.” <i>Id.</i> at 1:05-1:16 <p>NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “The NeuMoDx Molecular N96 and N288 are fully automated sample to result molecular diagnostics platforms. They provide continuous random access processing with initial results in one hour and operator walk away time of up to eight hours.” <i>Id.</i> at 0:00-0:18 • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins. During a series of independent heat on-heat off sequences, an optical scanner measures the level of fluorescence emitted, and converts it into the qualitative or quantitative results which are displayed as amplification

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		<p>curves for analysis by the laboratorian.” <i>Id.</i> at 3:58-4:26</p>  <p><i>NeuMoDx™</i> Molecular Systems, NEUMODx, http://www.neumodx.com/dr-steven-young-video-testimonial/, hyperlink at https://youtu.be/vukP6gbLBYE. (Exhibit 32)</p> <ul style="list-style-type: none"> At 2:58-3:18 (“There’s two systems that have been put into operation by NeuMoDx. One is the 288. It’s a high-throughput instrument, versus the 96, which is a lower throughput instrument.

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		<p>The advantage is that both systems use all of the same chemistry and all of the same hardware. Its just a smaller footprint.”)</p> <p>US9539576 (Exhibit 29)</p> <ul style="list-style-type: none"> Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising a heating surface configured to interface with a detection chamber and an inferior surface, inferior to the heating surface, including a connection point, wherein each of the set of heater-sensor dies includes a heating element and a sensing element; an electronics substrate, comprising a first substrate surface coupled to the inferior surface of each of the set of heater-sensor dies, a set of apertures longitudinally spaced across the electronics substrate and providing access through the electronics substrate to the set of heater-sensor dies, and a second substrate surface inferior to the first substrate surface, wherein the electronics substrate comprises a set of substrate connection points at least at one of the first substrate surface, an aperture surface defined within at least one of the set of apertures, and the second substrate surface, and wherein the electronics substrate couples the heating element and the sensing element of each of the set of heater-sensor dies to a controller; a set of heat-sink supports coupled to at least one of 1) the set of heater-sensor dies, through the set of apertures, and 2) the second substrate surface of the electronics substrate and configured to dissipate heat generated by the set of heater-sensor dies, wherein at least one of the set of heat-sink supports includes an integrated cooling element, and wherein a base surface of each of the set of heat-sink supports is coupled to an elastic element that transmits a biasing force through the electronics substrate, thereby maintaining thermal communication between the set of heater-sensor dies and a set of detection chambers upon alignment of the set of heater-sensor dies with the set of detection chambers; and a set of wire bonds, including a wire bond coupled between the connection point of at least one of the set of heater-sensor dies and one of the set of substrate connection points. <p>US9499896 (Exhibit 28)</p> <ul style="list-style-type: none"> Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising: an assembly including a first insulating layer, a heating region comprising an adhesion material layer coupled to the first insulating layer and a noble material layer coupled to the adhesion material

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		<p>layer, and a second insulating layer coupled to the heating region and to the first insulating layer through a pattern of voids in the heating region, wherein the pattern of voids in the heating region defines a coarse pattern, comprising a global morphology at a first scale and associated with a heating element of the heating region, and a fine pattern, comprising a local morphology at a second scale smaller than the first scale, integrated into the coarse pattern and associated with a sensing element of the heating region; an electronics substrate configured to couple heating elements and sensing elements of the set of heater-sensor dies to a controller; and a set of elastic elements coupled to a second substrate surface of the electronics substrate opposing a first substrate surface of the electronics substrate interfacing with the assemblies of the set of heater-sensor dies and configured to bias each of the set of heater-sensor dies against a detection chamber in a configuration wherein the set of heater-sensor dies is in thermal communication with a set of detection chambers.</p> <ul style="list-style-type: none"> U.S. Patent No. 9,499,896 at 9:11-19 (“As shown in FIGS. 1, 4A-4B, and 7A-7C, the system 100 can further comprise an electronics substrate 140 configured to couple heating and sensing elements of the set of heater-sensor dies to a controller 165, a set of heat-sink supports 150 configured to facilitate heat dissipation within the system 100, a set of elastic elements 160 configured to bias the set of heater-sensor dies 110 against detection chambers for sample processing, and can additionally comprise the controller 165 and/or a cooling subsystem 170.”)
1(m)	wherein the operating system is configured to actuate the lysing heater to heat the lysate solution in the lysing container to a first temperature	<p>The accused system comprises the operating system configured to actuate the lysing heater to heat the lysate solution in the lysing container to a first temperature.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “Each extraction plate well is then autonomously heated for as little as six minutes to ensure proper lysing and binding of the nucleic acids to the paramagnetic beads. The temperatures applied range from 37° C to over 90° C, resulting in the flexibility to process a wide variety of DNA and RNA IVD and LDT tests simultaneously.” 1:07-1:32 <p>40600106_ Rev-D-IFU-NeuMoDx-Lysis-Buffer-1-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 63)</p> <ul style="list-style-type: none"> The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/removal of inhibitors from

Claim	Claim Language	Infringement Evidence
		<p>unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with NeuMoDx Lysis Buffer 1 and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. NeuMoDx Lysis Buffer 1 is especially formulated and optimized for extraction of bacterial or viral DNA in plasma and serum samples, by providing an optimal environment for cell/particle lysis and DNA binding to occur. The stringent formulation of the buffer also inhibits or reduces any nuclease activity present in the sample thereby protecting the viral or bacterial DNA from degradation.</p> <p>40600105_Rev-D-IFU-NeuMoDx-Lysis-Buffer-2-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 64)</p> <ul style="list-style-type: none"> The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/removal of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed urine specimen is mixed with NeuMoDx Lysis Buffer 2 and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. NeuMoDx Lysis Buffer 2 is especially formulated and optimized for extraction of bacterial DNA from human urine samples, by providing an optimal environment for cell/particle lysis and DNA binding to occur. The stringent formulation of the buffer also inhibits or reduces any nuclease activity present in the sample thereby protecting the bacterial DNA from degradation. <p>40600104_Rev-D-IFU-NeuMoDx-Lysis-Buffer-3-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 65)</p> <ul style="list-style-type: none"> The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/removal of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of unprocessed specimen is mixed with NeuMoDx Lysis Buffer 3 and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. NeuMoDx Lysis Buffer 3 is especially formulated and optimized for extraction of viral RNA from human plasma and serum samples by providing an optimal environment for cell/particle lysis and nucleic acid binding to occur. The stringent formulation of the buffer also inhibits or reduces any nuclease activity present in the sample thereby protecting the viral RNA from degradation.

Claim	Claim Language	Infringement Evidence
		<p>40600103_Rev-D-IFU-NeuMoDx-Lysis-Buffer-4-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 66)</p> <ul style="list-style-type: none"> The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of enriched Lim Broth is mixed with NeuMoDx Lysis Buffer 4 and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres dried in the NeuMoDx Extraction Plate. <p>40600100_-Rev-D-IFU-NeuMoDx-WASH-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 58)</p> <ul style="list-style-type: none"> The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. <p>40500098_D-IFU-NeuMoDx-Extraction-Plate-US-ONLY (Exhibit 59)</p> <ul style="list-style-type: none"> “Each 24-well NeuMoDx Extraction Plate contains dried, room-temperature stable reagents including proprietary coated magnetic microspheres, a lytic enzyme, and RNA and DNA Sample Process Controls. Components within the extraction plate work in conjunction with the appropriate NeuMoDx lysis buffer to lyse cells in a temperature dependent manner and bind the nucleic acid while reducing activity of any nucleases present in clinical samples. The Sample Process Controls bind to the magnetic microspheres at the same time as the target nucleic acid, and are carried throughout the extraction procedure, serving as internal controls to monitor for any inefficiencies in the extraction process and presence of PCR interference substances.” <i>Id.</i> at 1. “The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate lysis buffer in the NeuMoDx Extraction Plate and is subjected to lysis at pre-determined

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		<p>temperatures in the presence of lytic enzymes and magnetic microspheres.” <i>Id.</i> at 1.</p> <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> • “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System... The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.” <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> • Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10. • Claim 4: The method of claim 3, wherein incubating the moiety-sample mixture comprises heating the moiety-sample solution to a temperature in the range of 25-95°C for 5-60 minutes, thus simultaneously lysing the biological sample and facilitating binding of nucleic acid

Claim	Claim Language	Infringement Evidence
		<p>material of the biological sample to the set of affinity moiety-coated microparticles.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at col. 6:8-15 (“In a first example of Step S130, enteroviral particles are incubated and lysed at room temperature in the presence of detergent. In a variation of the first example, enteroviral particles treated with Proteinase K can be incubated and lysed within a modified temperature range of 37-60C for optimal activity of the proteinase enzyme.”) • U.S. Patent. No. 9,382,532 at col. 6:15-21 (“In a second example of Step S130, a nasal Swab containing Staphylococcus aureus bacteria is incubated at approximately 95 C to ensure thorough lysis of the gram positive bacteria. In variations of the second example, treatment of the bacterial sample with specific lytic enzymes (e.g., achromopeptidase or lysostaphin) can result in modified lysis temperature.”) • U.S. Patent No. 9,382,532 at col. 13:45-55 (“In the first example, 200LL of CSF was spiked with 2 ul of EV viral particle lysate and then mixed with 500LL of RNA Collection Buffer 1 (CBR-1) and 300 uL of nuclease-free water in examples of Steps S110 and S120. As a comparison, a similar amount of EV particle lysate was spiked into a 1 mL solution comprised of 500LL of CBR-1 buffer and 500LL of nuclease free water and processed simultaneously. In an example of Step S130, RNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 60 C.”) • U.S. Patent No. 9,382,532 at col. 14:9-18 (“In the second example, 500 uL of M4 transport media containing a nasal Swab (donor) was spiked with 2Lofeithera 10 dilution (high) or a 10' (low) dilution of EV RNA (purified from 200 uL viral particle lysate and eluted in 20 u, total volume) and then mixed with 500 uL of RNA Collection Buffer 1 (CBR-1) and 0.4 mg of Proteinase K in examples of Steps S110 and S120. RNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 60C in an example of Step S130.”) • U.S. Patent No. 9,382,532 at 14:45-53 (“In the third example, 500 uL of UTM transport media containing a nasal swab (donor) was spiked with 2 uL of a 10" dilution of EV RNA (purified from 200 uL viral particle lysate and eluted in 20 uL total volume) and then mixed with 500 uL of RNA Collection Buffer 1 (CBR-1) and 0.6 mg of Proteinase K in examples of Steps S110 and S120. RNA was allowed to bind to the PAA affinity particles coated onto magnetic microparticles for 10 minutes at 60 C in an example of Step S130.”) • U.S. Patent No. 9,382,532 at 15:12-19 (“In the fourth example, 500 uL of M4 transport media containing a nasal Swab (donor) was spiked with 2 uL, often-fold dilutions of EV viral particle lysate and then mixed with 500 uL of RNA Collection Buffer 1 (CBR-1) and 0.4 mg of

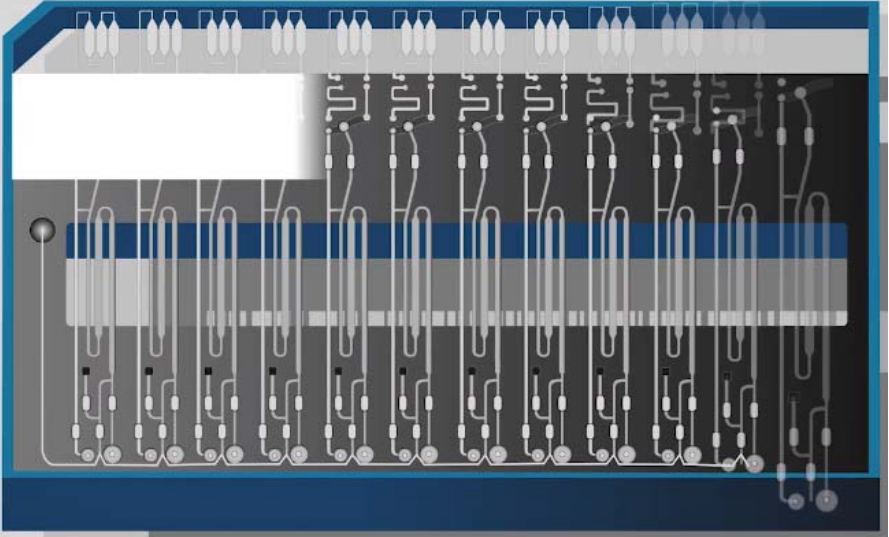
Claim	Claim Language	Infringement Evidence
		<p>Proteinase K in examples of Steps S110 and S120. RNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 60C in an example of Step S130.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,382,532 at 15:63-16:6 (“In the fifth example, 500 uL of Urine or Plasma was spiked with 10 pg of GBS DNA and then mixed with 500 uL of DNA Collection Buffer 2 (CBD-2) in examples of Steps S110 and S120. Alternately, a buccal Swab was added to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg Proteinase K and then spiked with 10 pg of GBS DNA in other examples of Steps S110 and S120. DNA was allowed to bind to the DABAM affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature or 60 C depending on matrix used in examples of Step S130.”) U.S. Patent No. 9,382,532 at 17:31-37 (“In the eighth example, a buccal Swab (obtained from a donor) was added to 1 mL of DNA Collection Buffer 1 (CBD 1) containing 0.4 mg. Proteinase K and then spiked with 10 pg of GBS DNA in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37C in an example of Step S130.”) U.S. Patent No. 9,382,532 at col. 28:49-51 (“CBD-1 (SP1: ultrapure water (93.1 mL), 1 M Tris pH 7.0 (50 mL), sodium citrate (50.88 g), boric acid (1.24 g), 0.5M EDTA pH 8.0 (2 mL), and Triton-X 100 (10 mL).”) U.S. Patent No. 9,382,532 at col. 17:64-18:8 (“In the ninth example 500 uL of M4 Transport Media (M4) or Universal Transport Media (UTM) containing a buccal Swab (obtained from a donor) was spiked with 10pg of GBS DNA and then mixed with 500 uL of DNA Collection Buffer 3 (CBD-3) and 0.4 mg of Proteinase K in examples of Steps S110 and S120. For comparison, “Dry Swab’ samples were prepared by adding a buccal swab to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg Proteinase K and then spiked with 10 pg of GBS DNA. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37C in an example of Step S130.”) U.S. Patent No. 9,382,532 at col. 28:55-57 (“CBD-3 ISP3: ultrapure water (862 mL), 1 M Tris pH 7.0 (100 mL), sodium citrate (11.76 g), boric acid (2.48 g), 0.5M EDTA pH 8.0 (4 mL), and Triton-X 100 (20 mL).”) U.S. Patent 9,382,532 at col. 18:34-41 (“In the tenth example, 100 uL whole blood (donor, obtained from Bioreclamation, Inc.) was added to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg. Proteinase K and then spiked with 10pg of GBS DNA in examples of Steps


Claim	Claim Language	Infringement Evidence
		<p>S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37 C in an example of Step S130.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,382,532 at col. 21:27-33 (“In the fifteenth example, 500 uL of Urine (obtained from a donor) was spiked with mpg of GBS DNA and then mixed with 500 uL of DNA Collection Buffer 2 (CBD-2) in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature, 37 C, 45C, or 60 C in examples of Step S130.”) U.S. Patent No. 9,382,532 at col. 28:52-54 (“CBD-2 SP2: ultrapure water (480 mL), 1 M Tris pH 7.0 (100 mL), sodium citrate (11.76 g), boric acid (2.48 g), 0.5M EDTA pH 8.0 (400 mL), and Triton-X 100 (20 mL).”) U.S. Patent No. 9,382,532 at col. 22:37-43 (“In the seventeenth example, 500 uL of M4 was spiked with ten-fold serial dilutions of 1 uL of EV viral particle lysate and 1 uL of GBSDNA and then mixed with 500 uL of RNA Collection Buffer 3 (CBR-3) in examples of Steps S110 and S120. RNA and DNA were allowed to bind to the PAA affinity moieties for 10 minutes at 37 C in an example of Step S130.”) U.S. Patent No. 9,382,532 at col. 28:46-48 (“CBR-3 2x EDTA only Buffer: ultrapure water (560 mL), 1M Tris pH 8.0 (20 mL), 0.5M EDTA pH 8.0 (400 mL), and Triton-X 100 (20 mL).”) <p>US9540636 (Exhibit 54)</p> <ul style="list-style-type: none"> Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the first fluidic pathway of the cartridge; and washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of

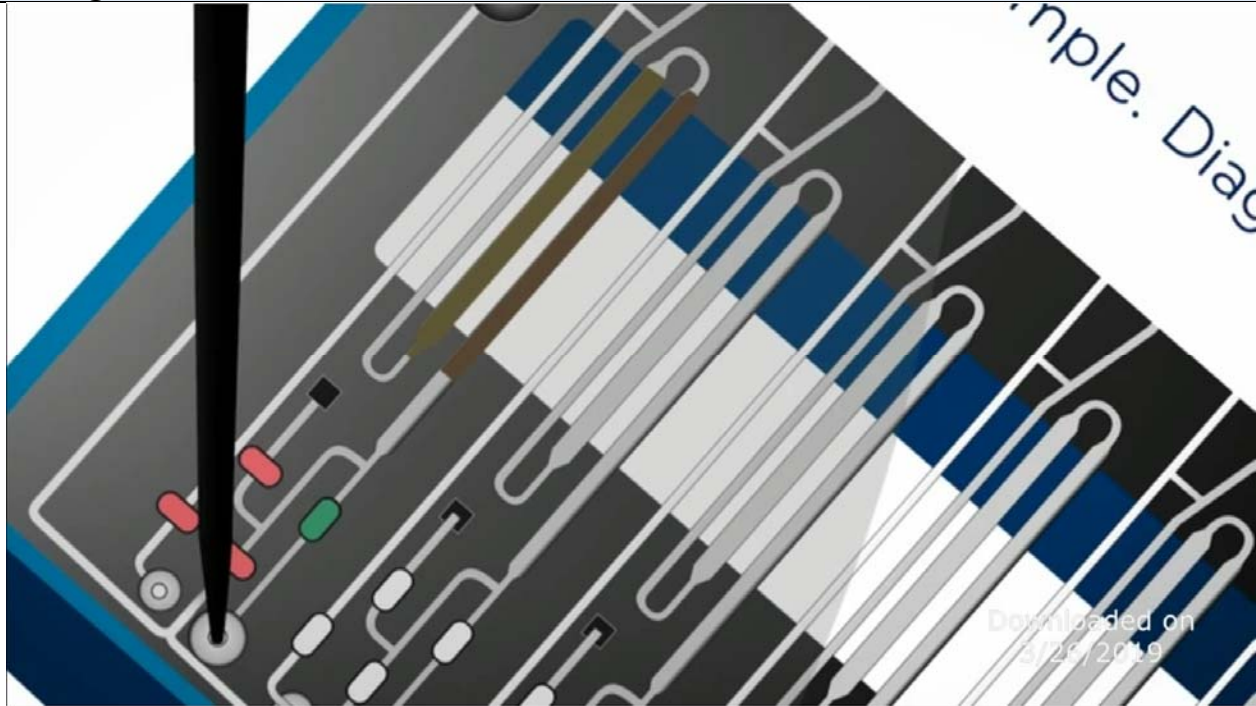
Claim	Claim Language	Infringement Evidence
		<p>pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway.</p> <ul style="list-style-type: none"> • Claim 6: The method of claim 3, wherein incubating the moiety-sample mixture comprises heating the moiety-sample solution to a temperature above 25° C for at least 5 minutes, thus simultaneously lysing the biological sample and facilitating the binding of nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles. • U.S. Patent No. 9,540,636 at col. 6:2-9 (“Preferably, the process chamber containing the moiety-sample solution (e.g., lysis, clean-up, binding reagents and the biological sample) is incubated for a defined period of time at a temperature preferably in the range of 25-95 C, wherein time and temperature parameters are biological sample-dependent. Example parameters for different biological samples are described briefly below, and further in Section 3 below.”) • U.S. Patent No. 9,540,646 at col. 6:24-31 (“In a variation of the first example, enteroviral particles treated with Proteinase K can be incubated and lysed within a modified temperature range of 37-60C for optimal activity of the proteinase enzyme. In a second example of Step S130, a nasal Swab containing Staphylococcus aureus bacteria is incubated at approximately 95 C to ensure thorough lysis of the gram-positive bacteria.”) • U.S. Patent No. 9,540,636 at col. 14:48-56 (“In the second example, 500 uL of M4 transport media containing a nasal Swab (donor) was spiked with 2 L of either a 10 dilution (high) or a 10'(low) dilution of EV RNA (purified from 200 uL viral particle lysate and eluted in 20 u, total volume) and then mixed with 500 uL of RNA Collection Buffer 1 (CBR-1) and 0.4 mg of Proteinase K in examples of Steps S110 and S120. RNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 60 C. in an example of Step S130.”) • U.S. Patent No. 9.540,636 at col. 15:22-30 (“In the third example, 500 uL of UTM transport media containing a nasal swab (donor) was spiked with 2 ul of a 10" dilution of EV RNA (purified from 200 uL viral particle lysate and eluted in 20 uL total volume) and then mixed with 500 uL of RNA Collection Buffer 1 (CBR-1) and 0.6 mg of Proteinase K in examples of Steps S110 and S120. RNA was allowed to bind to the PAA affinity particles coated onto magnetic microparticles for 10 minutes at 60 C. in an example of Step S130.”) • U.S. Patent No. 9,540,636 at col. 15:60-67 (“In the fourth example, 500 uL of M4 transport media containing a nasal Swab (donor) was spiked with 2 LL of ten-fold dilutions of EV viral particle lysate and then mixed with 500 uL of RNA Collection Buffer 1 (CBR-1) and 0.4 mg of

Claim	Claim Language	Infringement Evidence
		<p>Proteinase K in examples of Steps S110 and S120. RNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 60 C. in an example of Step S130.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,540,636 at col. 16:48-58 (“In the fifth example, 500 uL of Urine or Plasma was spiked with 10pg of GBS DNA and then mixed with 500 uL of DNA Collection Buffer 2 (CBD-2) in examples of Steps S110 and S120. Alternately, a buccal swab was added to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg. Proteinase K and then spiked with 10 pg of GBS DNA in other examples of Steps S110 and S120. DNA was allowed to bind to the DABAM affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature or 60 C depending on matrix used in examples of Step S130.”) U.S. Patent No. 9,540,636 at col. 18: 31-37 (“In the eighth example, a buccal Swab (obtained from a donor) was added to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg. Proteinase K and then spiked with 10 pg of GBS DNA in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37 C in an example of Step S130.”) U.S. Patent No. 9,540,636 at col. 30:45-47 (“CBD-1 (SP1: ultrapure water (93.1 mL), 1 M Tris pH 7.0 (50 mL), sodium citrate (5.88 g), boric acid (1.24 g), 0.5M EDTA pH 8.0 (2 mL), and Triton-X 100 (10 mL).”) U.S. Patent No. 9,540,636 at col. 19:2-13 (“In the ninth example 500 uL of M4 Transport Media (M4) or Universal Transport Media (UTM) containing a buccal Swab (obtained from a donor) was spiked with 10 pg of GBS DNA and then mixed with 500 uL of DNA Collection Buffer 3 (CBD-3) and 0.4 mg of Proteinase K in examples of Steps S110 and S120. For comparison, “Dry Swab” samples were prepared by adding a buccal swab to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg. Proteinase K and then spiked with 10 pg of GBS DNA. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37 C in an example of Step S130.”) U.S. Patent No. 9,540,636 at col. 30:51-53 (“CBD-3 ISP3: ultrapure water (862 mL), 1 M Tris pH 7.0 (100 mL), sodium citrate (11.76 g), boric acid (2.48 g), 0.5M EDTA pH 8.0 (4 mL), and Triton-X 100 (20 mL).”) U.S. Patent No. 9,540,636 at col. 19:44-50 (“In the tenth example, 100 uL whole blood (donor, obtained from Bioreclamation, Inc.) was added to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg. Proteinase K and then spiked with 10 pg of GBS DNA in examples of Steps

Claim	Claim Language	Infringement Evidence
		<p>S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37 C in an example of Step S130.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 30:48-50 (“CBD-2 SP2: ultrapure water (480 mL), 1 M Tris pH 7.0 (100 mL), sodium citrate (11.76 g), boric acid (2.48 g), 0.5M EDTA pH 8.0 (400 mL), and Triton-X 100 (20 mL).”) • U.S. Patent No. 9,540,636 at col. 24:16-22 (“In the seventeenth example, 500 uL of M4 was spiked with ten-fold serial dilutions of 1 uL of EV viral particle lysate and 1 LL of GBS DNA and then mixed with 500 uL of RNA Collection Buffer 3 (CBR-3) in examples of Steps S110 and S120. RNA and DNA were allowed to bind to the PAA affinity moieties for 10 minutes at 37C in an example of Step S130.”)
1(n)	wherein the first processing region of the microfluidic network is configured to receive the lysate solution and the plurality of magnetic binding particles from the lysing container	<p>The accused system comprises the first processing region of the microfluidic network configured to receive the lysate solution and the plurality of magnetic binding particles from the lysing container.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “After thoroughly mixing the solution in each well of the extraction plate, the crude lysate is independently aspirated from each well and transferred to the NeuMoDx cartridge.” <i>Id.</i> at 1:35-1:51. • 1:51 “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” • 1:56 Microfluidic cartridge

Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none"> • 2:02 “The liquid handling robot employs total aspiration and dispense monitoring pressure sensing to ensure each tip is securely seated into one of the 12 independent sample ports or s-ports of the cartridge. Once the pipette tip is secured, the entire volume of solution will be dispensed.” • 2:07 Dispensing into the s-ports

Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none"> • 2:24 “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” • 2:28 Lysate in the s-channel (extraction)

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		 <p data-bbox="634 1003 1982 1040">40600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 20)</p> <ul data-bbox="688 1047 1982 1226" style="list-style-type: none"> • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p data-bbox="634 1263 1545 1300">40500098_D-IFU-NeuMoDx-Extraction-Plate-US-ONLY (Exhibit 59)</p> <ul data-bbox="688 1307 1982 1409" style="list-style-type: none"> • “The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the

Claim	Claim Language	Infringement Evidence
		<p>NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution.” <i>Id.</i> at 1.</p> <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound nucleic acid is eluted using the NeuMoDx™ RELEASE Solution. <p>40600106_Rev-D-IFU-NeuMoDx-Lysis-Buffer-1-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 63)</p> <ul style="list-style-type: none"> • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600105_Rev-D-IFU-NeuMoDx-Lysis-Buffer-2-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 64)</p> <ul style="list-style-type: none"> • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600104_Rev-D-IFU-NeuMoDx-Lysis-Buffer-3-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 65)</p> <ul style="list-style-type: none"> • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™

Claim	Claim Language	Infringement Evidence
		<p>Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution.</p> <p>40600100_-Rev-D-IFU-NeuMoDx-WASH-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 58)</p> <ul style="list-style-type: none"> • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>US10010888 (Exhibit 55)</p> <ul style="list-style-type: none"> • Claim 16. The method of claim 14, wherein transferring the nucleic acid-magnetic bead sample in to the fluidic pathway of the cartridge comprises transferring the nucleic acid-magnetic bead sample into an s-shaped capture segment passing between the heating region and the magnet housing region of the cartridge. • U.S. Patent No. 10,010,888 at col. 33:12-17 (“Step S430 recites transferring each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways, and functions to isolate each of the set of nucleic acid-magnetic bead samples within separate pathways for further processing.”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 2. The system of claim 1, further comprising a liquid handling system configured to transfer at least one magnetic bead-sample from the capture plate to the molecular diagnostic module, and to aspirate at least one nucleic acid volume from the molecular diagnostic module. • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprising a segment

Claim	Claim Language	Infringement Evidence
		<p>configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer.</p> <ul style="list-style-type: none"> • Claim 24. The system of claim 23, further comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample, a lysing reagent, and a sample process control, wherein the capture plate facilitates production of at least one biological sample combined with magnetic beads; an assay strip comprising at least one reagent well containing molecular diagnostic reagent volume configured to be combined with a nucleic acid volume of the set of nucleic acid volumes to produce at least one nucleic acid-reagent mixture; and a liquid handling system configured to transfer at least one biological sample combined with magnetic beads from the capture plate to the molecular diagnostic module, transfer at least one nucleic acid-reagent mixture from the assay strip back to the molecular diagnostic module. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) • U.S. Patent No. 9,050,594 at col. 3:33-41 (“The liquid handling system 250 then aspirates substantially all of each sample of the set of lysed biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate no, and dispenses the set of magnetic bead-samples into a microfluidic cartridge 210, aligned within a cartridge receiving module 140 of a molecular diagnostic module 130, and configured to be manipulated by the molecular diagnostic module 130.”) • U.S. Patent no. 9,050,594 at col 28:53-58 (“Step S430 recites transferring each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic path-ways, and functions to isolate each of the set of nucleic

Claim	Claim Language	Infringement Evidence
		<p>acid-magnetic bead samples within separate pathways for further processing.”)</p> <p>US9441219 (Exhibit 53)</p> <ul style="list-style-type: none"> Claim 7: The molecular diagnostic module of claim 1, further comprising: a capture plate comprising a well containing a set of magnetic beads, a lysing reagent, and a sample process control, configured to be combined with the biological sample, wherein the capture plate facilitates production of a magnetic bead-sample from the biological sample and the set of magnetic beads; an assay strip comprising a reagent well containing a molecular diagnostic reagent volume configured to be combined with the nucleic acid volume processed from the magnetic-bead sample, thereby generating a nucleic acid-reagent mixture; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the cartridge, transfer the nucleic acid volume from the cartridge to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip back to the cartridge. Claim 14. The system of claim 8, further comprising a capture plate comprising a well containing a set of magnetic beads, a lysing reagent, and a sample process control, configured to be combined with the biological sample, wherein the capture plate facilitates production of a magnetic bead-sample from the biological sample and the set of magnetic beads; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the cartridge, and configured to transfer a nucleic acid volume processed from the magnetic bead-sample from the cartridge. U.S. Patent No. 9,441,219 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids. U.S. Patent No. 9,441,219 at col. 3:28-35 (“The liquid handling system 250 then aspirates

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		<p>substantially all of each sample of the set of lysed biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate no, and dispenses the set of magnetic bead-samples into a microfluidic cartridge 210, aligned within a cartridge receiving module 140 of a molecular diagnostic module 130, and configured to be manipulated by the molecular diagnostic module 130.”</p> <ul style="list-style-type: none"> U.S. Patent No. 9,441,219 at col. 29:30-35 (“Step S430 recites transferring each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways, and functions to isolate each of the set of nucleic acid-magnetic bead samples within separate pathways for further processing.”) <p>US9540636 (Exhibit 54)</p> <ul style="list-style-type: none"> Claim 5. The method of claim 4, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety sample mixture from the process chamber, occluding the fluidic pathway of the cartridge at a set of occlusion positions upon displacement of pins of the set of pins to generate a path through a magnetic field, and to a waste chamber, and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber. Claim 7. The method of claim 3, wherein washing the set of moiety-bound nucleic acid particles comprises aspirating the moiety-sample mixture; receiving the cartridge at the cartridge receiving module comprising the set of pins and a cam card interfacing with the set of pins; transitioning the cartridge to an active configuration that disposes the cartridge to a position that is proximal to the set of pins; displacing the first subset of the set of pins in the active configuration of the cartridge, upon translation of the cam card relative to the set of pins, thereby occluding the fluidic pathway of the cartridge at a set of occlusion positions; delivering the moiety-sample mixture into the fluidic pathway, wherein the fluidic pathway is configured to pass through a magnetic field and is coupled to a waste chamber, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field; and delivering a wash solution through the fluidic pathway and into the waste chamber in a continuous flow operation. Claim 10. The method of claim 3, further comprising releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles, wherein releasing the nucleic acid sample comprises:

Claim	Claim Language	Infringement Evidence
		<p>occluding the fluidic pathway of the cartridge, comprising the process chamber, at a set of occlusion positions, upon displacement of pins of the set of pins, to define a path through a magnetic field; delivering the set of moiety-bound nucleic acid particles into the path of the fluidic pathway; and delivering an elution solution into the fluidic pathway, thereby inducing a pH shift configured to release the nucleic acid sample from the set of moiety-bound nucleic acid particles.</p> <p>US9604213 (Exhibit 30)</p> <ul style="list-style-type: none"> • Claim 1. A system for processing and detecting nucleic acids in cooperation with a cartridge comprising a heating region defined at a first surface, and a magnet housing region defined at a second surface in thermal communication with the first surface, the system comprising: a capture plate configured to facilitate combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate and separate nucleic acids from the set of magnetic beads, comprising: a cartridge platform configured to receive the cartridge and comprising a magnet receiving slot aligned with the second Surface during operation, a heater configured to transmit heat to the heating region at the first Surface during operation, and a magnet coupled to a magnet heating element that heats the magnet during operation with the magnet proximal the second Surface, the magnet configured to pass through the magnet receiving slot into the magnet housing region during operation, thereby facilitating separation of a nucleic acid Volume from the magnetic bead-sample and heating of the magnetic bead-sample in cooperation with the heater • Claim 8. The system of claim 1, further comprising a liquid handling system configured to transfer the magnetic bead sample from the capture plate to the molecular diagnostic module, and to aspirate the nucleic acid volume from the molecular diagnostic module. • U.S. Patent No. 9,604,213 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling Subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation Subsystem configured to control fluid flow through a microfluidic

Claim	Claim Language	Infringement Evidence
		<p>cartridge for processing nucleic acids, and an optical Subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay Strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,604,213 at col. 3:28-35 (“The liquid handling system 250 then aspirates substantially all of each sample of the set of lysed biological samples combined with magnetic beads (i.e., set of magnetic bead samples) from the capture plate no, and dispenses the set of magnetic bead-samples into a microfluidic cartridge 210, aligned within a cartridge receiving module 140 of a molecular diagnostic module 130, and configured to be manipulated by the molecular diagnostic module 130.”)
1(o)	wherein the waste chamber is configured to receive excess lysate solution downstream of the first processing region as the plurality of magnetic binding particles are retained in the first processing region	<p>The accused system comprises the waste chamber configured to receive excess lysate solution downstream of the first processing region as the plurality of magnetic binding particles are retained in the first processing region.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “A precise volume of air is then applied to remove any remaining liquid into the waste chamber. NeuMoDx wash solution is pumped via the fluid port into the microfluidic cartridge to remove all unbound material, followed by another volume of air to remove excess wash solution.” <i>Id.</i> at 2:39-2:43. <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position of the fluidic pathway, by way of the void of the corrugated surface, the fluidic

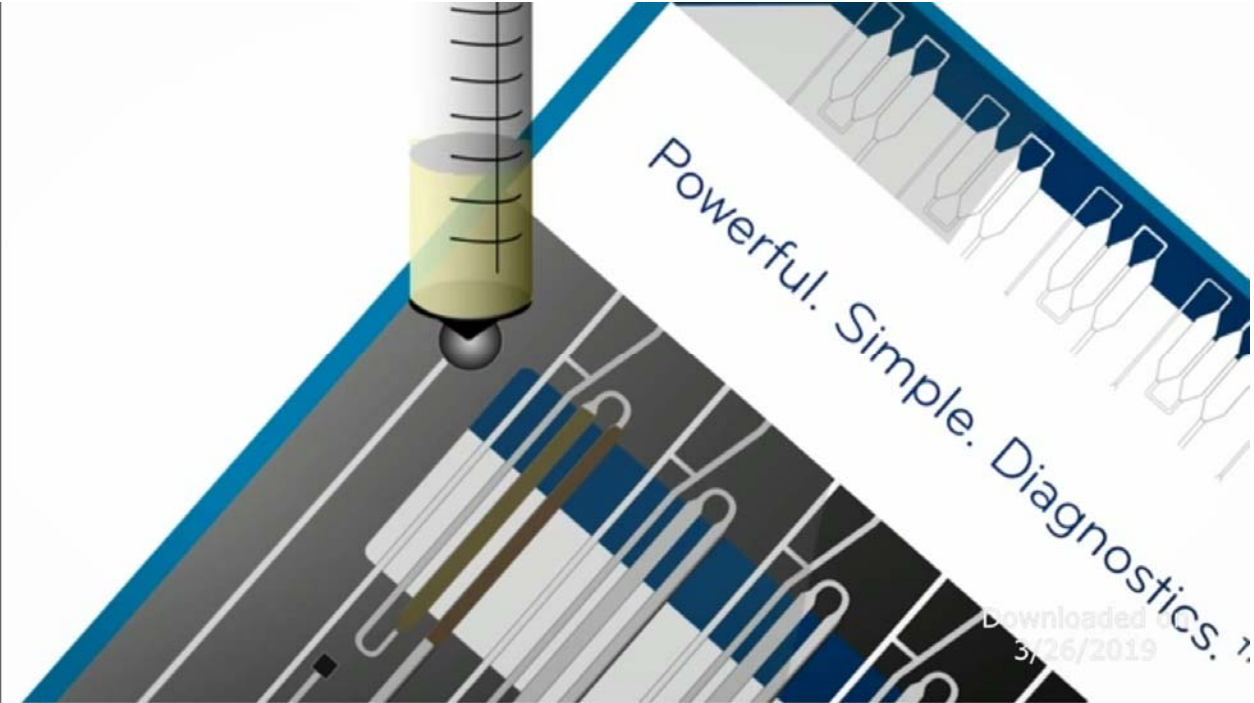
Claim	Claim Language	Infringement Evidence
		<p>pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber.</p> <ul style="list-style-type: none"> • Claim 3. The cartridge of claim 1, wherein the waste chamber comprises at least one waste inlet in communication with the opening of the intermediate substrate, and wherein the corrugated surface of the waste chamber further defines a rectangular prismatic void spanning a long dimension of the cartridge that defines a magnet housing region configured to reversibly receive a magnet from the direction perpendicular to a broad face of the first layer, and configured to cross the fluidic pathway. • Claim 5. The cartridge of claim 4, wherein the fluidic pathway is configured to transfer waste fluid of the sample to the waste chamber through a first waste inlet upstream of the capture segment by way of a first waste segment fluidly coupled to the fluid waste inlet and an initiating portion of the capture segment, and wherein the fluidic pathway is configured to transfer a second waste fluid to the waste chamber through a second waste inlet downstream of the capture segment by way of a second waste segment fluidly coupled to the second waste inlet and a terminating portion of the capture segment. • U.S. Patent No. 9,403,165 at Abstract (“A microfluidic cartridge, configured to facilitate processing and detection of nucleic acids, comprising: a top layer comprising a set of cartridge-aligning indentations, a set of sample port-reagent port pairs, a shared fluid port, a vent region, a heating region, and a set of detection chambers; an intermediate substrate, coupled to the top layer comprising a waste chamber, an elastomeric layer, partially situated on the intermediate Substrate; and a set of fluidic pathways, each formed by at least a portion of the top layer and a portion of the elastomeric layer, wherein each fluidic pathway is fluidically coupled to a sample port-reagent port pair, the shared fluid port, and a detection chamber, comprises a turnabout portion passing through the heating region, and is configured to be occluded upon deformation of the elastomeric layer, to transfer a waste fluid to the waste chamber, and to pass through the vent region.”) • U.S. Patent No. 9,403,165 at 8:24-32 (“As shown in FIG. 1B, an embodiment of the microfluidic cartridge also comprises an intermediate substrate 120, coupled to the top layer 110 and partially separated from the top layer 110 by a film layer 125, configured to form a waste chamber 130. The intermediate substrate 120 functions to serve as a substrate to which layers of the microfluidic cartridge may be bonded, to provide guides for the valve pins, and to provide a waste chamber volume into which a waste fluid may be deposited.”)


Claim	Claim Language	Infringement Evidence
		<p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at Abstract (“A microfluidic cartridge, configured to facilitate processing and detection of nucleic acids, comprising: a top layer comprising a set of cartridge-aligning indentations, a set of sample port-reagent port pairs, a shared fluid port, a vent region, a heating region, and a set of detection chambers; an intermediate substrate, coupled to the top layer comprising a waste chamber; an elastomeric layer, partially situated on the intermediate substrate; and a set of fluidic pathways, each formed by at least a portion of the top layer and a portion of the elastomeric layer, wherein each fluidic pathway is fluidically coupled to a sample port-reagent port pair, the shared fluid port, and a Detection chamber, comprises a turnabout portion passing through the heating region, and is configured to be occluded upon deformation of the elastomeric layer, to transfer a waste fluid to the waste chamber, and to pass through the vent region.”) US Patent No. 9,738,887 at 13:35-42. (“The set of fluidic pathways 160 of the microfluidic cartridge 100 functions to provide a fluid network into which volumes of sample fluids, reagents, buffers and/or gases used in a molecular diagnostics protocol may be delivered, out of which waste fluids may be eliminated, and by which processed nucleic acid samples may be delivered to a detection chamber for analysis, which may include amplification and/or detection.”) <p>US9101930 (Exhibit 25)</p> <ul style="list-style-type: none"> Claim 10. A cartridge, configured to facilitate processing and detecting of nucleic acids, comprising: a first layer and an intermediate substrate, coupled to the first layer, wherein the intermediate substrate defines a waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids spanning a majority of a width of the intermediate substrate and external to the waste chamber, wherein the set of voids is accessible from a direction perpendicular to a broad surface of the first layer; a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway, formed by at least a portion of the first layer, wherein the first fluidic pathway and the second fluidic pathway are each superior to the intermediate substrate, are each at least partially separated from the corrugated surface of the intermediate substrate by an elastomeric layer and are each configured to transfer waste to the waste chamber through a set of openings of the intermediate substrate.

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> U.S. Patent No. 9,101,930 at Abstract (“A microfluidic cartridge, configured to facilitate processing and detection of nucleic acids, comprising: a top layer comprising a set of cartridge-aligning indentations, a set of sample port-reagent port pairs, a shared fluid port, a vent region, a heating region, and a set of detection chambers; an intermediate substrate, coupled to the top layer comprising a waste chamber, an elastomeric layer, partially situated on the intermediate substrate; and a set of fluidic pathways, each formed by at least a portion of the top layer and a portion of the elastomeric layer, wherein each fluidic pathway is fluidically coupled to a sample port-reagent port pair, the shared fluid port, and a Detection chamber, comprises a turnabout portion passing through the heating region, and is configured to be occluded upon deformation of the elastomeric layer, to transfer a waste fluid to the waste chamber, and to pass through the vent region.”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprising a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. <p>US9452430 (Exhibit 56)</p> <ul style="list-style-type: none"> Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port; an intermediate substrate that is coupled to the first layer, partially separated from the first layer by a film layer, and configured to form a sealed waste chamber and a waste port into the sealed waste chamber, wherein the sealed waste chamber directly opposes the first layer across the film layer and defines an external void; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the sealed waste chamber by a deformably layer, wherein the fluidic pathway is fluidly coupled to the sample port, and wherein, upon deformation of the deformable layer through the external void defined by the waste chamber, the fluidic pathway is occluded and configured to transfer waste fluid of the sample through the waste port into an interior portion of the sealed waste chamber.

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> Claim 11. The cartridge for processing of a set of samples, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate forms a sealed waste chamber and a set of waste ports into the sealed waste chamber, wherein the sealed waste chamber directly opposes the first layer across the film layer and defines an external void; a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the first layer, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the sealed wax chamber by a deformable layer that is deformed through the external void, and each of the first and second fluidic pathways is configured to transfer waste fluid of the set of samples into the sealed waste chamber through the set of waste ports. Claim 12. The cartridge of claim 11, wherein the deformable layer includes a set of waste openings aligned with the set of waste ports, thereby allowing transfer of waste fluid from the set of samples into the sealed waste chamber. U.S. Patent No. 9,452,430 at Abstract (“A microfluidic cartridge, configured to facilitate processing and detection of nucleic acids, comprising: a top layer comprising a set of cartridge-aligning indentations, a set of sample port-reagent port pairs, a shared fluid port, a vent region, a heating region, and a set of Detection chambers; an intermediate Substrate, coupled to the top layer comprising a waste chamber; an elastomeric layer, partially situated on the intermediate substrate; and a set of fluidic pathways, each formed by at least a portion of the top layer and a portion of the elastomeric layer, wherein each fluidic pathway is fluidically coupled to a sample port-reagent port pair, the shared fluid port, and a Detection chamber, comprises a turnabout portion passing through the heating region, and is configured to be occluded upon deformation of the elastomeric layer, to transfer a waste fluid to the waste chamber, and to pass through the vent region.”) <p>US9540636 (Exhibit 54)</p> <ul style="list-style-type: none"> Claim 5. The method of claim 4, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety sample mixture from the process chamber, occluding the fluidic pathway of the cartridge at a set of occlusion positions upon displacement of pins of the set of pins to generate a path through a magnetic field, and to a waste chamber, and delivering the moiety-sample mixture through the path of the fluidic

Claim	Claim Language	Infringement Evidence														
		<p>pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber.</p> <ul style="list-style-type: none">U.S. Patent No. 9,540,636 at col. 3:14-25 (“As shown in FIGS. 1A and 2, a method 100 for nucleic acid isolation comprises receiving a binding moiety solution within a process chamber S110; mixing the binding moiety solution with a biological sample, within the process chamber, in order to produce a moiety-sample solution S120; incubating the moiety-sample solution during a time window S130, thereby producing a lysed solution comprising a moiety-bound nucleic acid volume and a waste volume; separating the moiety-bound nucleic acid volume from the waste volume S140; washing the moiety-bound nucleic acid volume S150; and releasing a nucleic acid sample from the moiety-bound nucleic acid volume S160.”)U.S. Patent No. 9,540,636 at col. 6:34-37 (“In all of the specific examples and variations, the incubation produces a lysed moiety-sample solution comprising a volume of affinity moiety-bound nucleic acids and a waste volume for removal.”)														
1(p)	wherein the microfluidic network is configured to receive a wash solution in the first processing region to remove unbound material not retained by the plurality of magnetic binding particles	<p>The accused system comprises the microfluidic network configured to receive a wash solution in the first processing region to remove unbound material not retained by the plurality of magnetic binding particles.</p> <p>406001113 Rev-A-SDS-NeuMoDx-Wash-Solution-FINAL.pdf (Exhibit 72)</p> <table><tr><td colspan="2"><u>General Information</u></td></tr><tr><td>Form:</td><td>Liquid</td></tr><tr><td>Color:</td><td>Clear</td></tr><tr><td>Odor:</td><td>Odorless</td></tr><tr><td>pH Value at 20°C (68°F)</td><td>pH 7.0-8.1</td></tr><tr><td>melting point/melting range:</td><td>Not determined</td></tr><tr><td>Boiling point/boiling range:</td><td>Not determined</td></tr></table> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936 (Exhibit 16)</p> <ul style="list-style-type: none">2:39 “A precise volume of air is then applied to remove any remaining liquid into the waste chamber. NeuMoDx wash solution is pumped via the fluid port into the microfluidic cartridge to remove all unbound material, followed by another volume of air to remove excess	<u>General Information</u>		Form:	Liquid	Color:	Clear	Odor:	Odorless	pH Value at 20°C (68°F)	pH 7.0-8.1	melting point/melting range:	Not determined	Boiling point/boiling range:	Not determined
<u>General Information</u>																
Form:	Liquid															
Color:	Clear															
Odor:	Odorless															
pH Value at 20°C (68°F)	pH 7.0-8.1															
melting point/melting range:	Not determined															
Boiling point/boiling range:	Not determined															

Claim	Claim Language	Infringement Evidence
		<p>wash solution.” <i>Id.</i> at 2:39-2:43.</p> <ul style="list-style-type: none">• 2:43 Wash solution  <ul style="list-style-type: none">• 2:45 Wash solution in s-channel

Claim	Claim Language	Infringement Evidence
		 <p>40600106_ Rev-D-IFU-NeuMoDx-Lysis-Buffer-1-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 63)</p> <ul style="list-style-type: none"> • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600105_ Rev-D-IFU-NeuMoDx-Lysis-Buffer-2-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 64)</p> <ul style="list-style-type: none"> • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution.

Claim	Claim Language	Infringement Evidence
		<p>40600104_Rev-D-IFU-NeuMoDx-Lysis-Buffer-3-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 65)</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600103_Rev-D-IFU-NeuMoDx-Lysis-Buffer-4-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 66)</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600100_-Rev-D-IFU-NeuMoDx-WASH-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 58)</p> <ul style="list-style-type: none"> The NeuMoDx WASH Solution is a proprietary reagent that removes unbound/non-specifically bound moieties including PCR inhibitors from the magnetic microspheres bound with nucleic acid. It is formulated to work with the proprietary NeuMoDx Extraction Plate reagents to enable the removal of unnecessary material while leaving the desired nucleic acid bound to the magnetic microspheres. The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600146_D-IFU-NeuMoDx-LDT-Master-Mix-RNA-US-ONLY (Exhibit 62)</p> <ul style="list-style-type: none"> “NeuMoDx™ LDT Master Mix, RNA: Instructions for Use...Upon lysis, the released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound RNA is eluted using NeuMoDx™ RELEASE Solution.” <p>40600145_-Rev-D-IFU-NeuMoD-LDT-Master-Mix-DNA-US-ONLY-FINAL-25Oct2018.pdf (Exhibit</p>

Claim	Claim Language	Infringement Evidence
		<p>67)</p> <ul style="list-style-type: none"> “NeuMoDx™ LDT Master Mix, DNA: Instructions for Use...Upon lysis, the released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound DNA is eluted using NeuMoDx™ RELEASE Solution.” <p>40600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 20)</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound nucleic acid is eluted using NeuMoDx™ RELEASE Solution. <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> “NeuMoDx™ Cartridge: Instructions for Use...The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound nucleic acid is eluted using the NeuMoDx™ RELEASE Solution.” <p>40600129_D-IFU-GBS-Test-Strip-US-only.pdf (Exhibit 60)</p> <ul style="list-style-type: none"> “NeuMoDx™ GBS Test Strip: Instructions for Use...The released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are loaded into the NeuMoDx™ Cartridge where the unbound, non-DNA components are further washed away with NeuMoDx™ WASH Solution and the bound DNA is eluted using NeuMoDx™ RELEASE Solution.” <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to

Claim	Claim Language	Infringement Evidence
		<p>a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 19. A method for nucleic acid isolation from a biological sample, comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution includes a set of affinity moiety-coated microparticles, comprising a set of microparticles amide-bonded to at least one of poly(allylamine) of molecular weight <30,000 Da and Polypropylenimine tetramine dendrimer Generation 1; producing a moiety-sample mixture upon combination of the binding moiety solution with the biological sample; producing a set of moiety-bound nucleic acid particles upon incubation of the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of the set of pins includes reversing displacement of at least one pin of the first subset of the set of pins, and reversing occlusion of a portion of the fluidic pathway.

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> U.S. Patent No. 9,382,532 at col. 7:54-58 (“Step S150 recites washing the moiety-bound nucleic acid volume, and functions to enable the removal of non-specifically bound moieties and to facilitate a subsequent buffer change in Step S160 by displacing any liquid retained during Step S140.”) <p>US9540636 (Exhibit 54)</p> <ul style="list-style-type: none"> Claim 1: A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; and washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway.” Claim 17: A method for nucleic acid isolation from a biological sample, comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution includes a set of affinity moiety-coated microparticles; producing a moiety-sample mixture upon combination of the binding moiety solution with the biological sample; producing a set of moiety-bound nucleic acid particles upon incubation of the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles; occluding a fluidic pathway of a cartridge upon displacement of a first subset of pin at the cartridge comprising the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles, within the fluidic pathway of the cartridge; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an

Claim	Claim Language	Infringement Evidence												
		<p>elution solution.</p> <ul style="list-style-type: none">U.S. Patent No. 9,540,636 at Abstract (“A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, in order to produce a moiety-sample mixture; incubating the moiety-sample mixture during a time window, thereby producing a solution comprising a set of moiety-bound nucleic acid particles and a waste volume; separating the set of moiety-bound nucleic acid particles from the waste volume; washing the set of moiety-bound nucleic acid particles; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles.”)												
1(q)	a release solution having a pH of at least 11.4	<p>The accused system comprises a release solution having a pH of at least 11.4.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none">“A high pH NeuMoDx release reagent is dispensed into the s-channel to cover the beads and heat is applied to complete the denaturation process, resulting in released nucleic acid or eluent.” 2:55-3:10 <p>40600114_Rev-C-SDS-NeuMoDx-Release-Solution-FINAL.pdf (Exhibit 78)</p> <table><tr><th colspan="4">Hazardous chemical ingredients per U.S. OSHA criteria (29 CFR 1910.1200 Hazard Communication):</th></tr><tr><th>Chemical Name</th><th>Identifiers</th><th>Classification</th><th>Concentration Percentages are by weight</th></tr><tr><td></td><td></td><td></td><td></td></tr></table>	Hazardous chemical ingredients per U.S. OSHA criteria (29 CFR 1910.1200 Hazard Communication):				Chemical Name	Identifiers	Classification	Concentration Percentages are by weight				
Hazardous chemical ingredients per U.S. OSHA criteria (29 CFR 1910.1200 Hazard Communication):														
Chemical Name	Identifiers	Classification	Concentration Percentages are by weight											

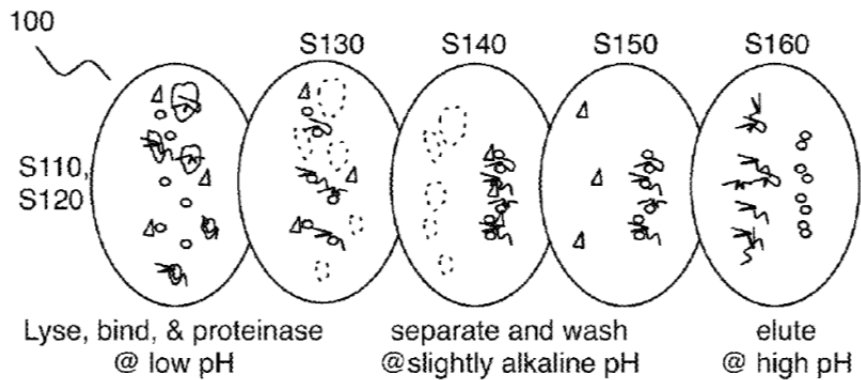
Claim	Claim Language	Infringement Evidence			
		Sodium Hydroxide (NaOH)	CAS-No. 1310-73-2 EC-No. 215-185-5 Index-No. 011-002-00-6 Registration No. 01-2119457892-27-XXXX	Metal Corrosive 1; Skin Corrosive 1B; Eye Damage 1; Aquatic Acute 3; H290, H314, H318, H402.	<1% (
		Deionized water	CAS-No. 7732-18-5	N/A	>99%
		<p>Odor: Odorless</p> <p>pH Value at 20°C (68°F) 11.8-12.8</p> <p>US9339812 (Exhibit 26)</p> <ul style="list-style-type: none"> Claim 7. The method of claim 6, wherein separating the volume of nucleic acids from the biological sample further comprises dispensing a release solution through the fluidic pathway by the fluid port. Claim 8. The method of claim 7, wherein separating the volume of nucleic acids from the biological sample further comprises heating the first portion of the fluidic pathway to facilitate a pH shift, thus releasing nucleic acids from magnetic beads to produce the volume of nucleic acids. Claim 20. The method of claim 19, wherein producing the set of nucleic acid volumes from the set of nucleic acid-magnetic bead samples comprises: upon passing a magnet through one of the set of slots of the cartridge platform of the molecular diagnostic module, providing a magnetic field spanning a portion of each fluidic pathway in the set of fluidic pathways, thus capturing the set of nucleic acid-magnetic bead samples; dispensing a wash solution into each fluidic pathway of the set of fluidic pathways; dispensing a release solution into each fluidic pathway of the set of fluidic pathways; and heating each fluidic pathway of the set of fluidic pathways to facilitate a pH shift, thus unbinding nucleic acids from magnetic beads to produce the set of nucleic acid volumes. U.S. Patent No. 9,339,812 at col. 10:49-52 (“The cartridge heater functions to transfer heat to 			

Claim	Claim Language	Infringement Evidence
		<p>a heating region of a microfluidic cartridge, for inducing a pH shift to release bound nucleic acids from magnetic beads within the heating region 224.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,339,812 at col. 29:50-53 (“Step S442 functions to provide a heater, which, in combination with a release solution that provides a pH shift, facilitate a rapid and efficient unbinding of the nucleic acids from magnetic beads.”) <p>US9540636 (Exhibit 54)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,540,636 at col. 14:22-28 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 500 uL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) U.S. Patent No. 9,540,636 at col. 30:60-61 (“ELUTION SOLUTION ELU-2 40 mM NaOH: ultrapure water (960 mL) and 1N NaOH (40 mL).”) U.S. Patent No. 9,540,636 at col. 14:57-63 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 250 uL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) U.S. Patent No. 9,540,636 at col. 15:31-36 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL or 250 uL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”) U.S. Patent No. 9,540,636 at col. 15:67-16:6 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”) U.S. Patent No. 9,540,636 at col. 16:57-64 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-1 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) U.S. Patent No. 9,540,636 at col. 30:58-59 (“ELUTION SOLUTION ELU-1 20 mM NaOH:

Claim	Claim Language	Infringement Evidence
		<p>ultrapure water (980 mL) and 1N NaOH (20 mL).”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 17:29-34 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 17:66-18:5 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the magnetic microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 18:37-43 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 19:13-19 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 19:51-57 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed twice with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 20:37-43 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 21:9-16 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL

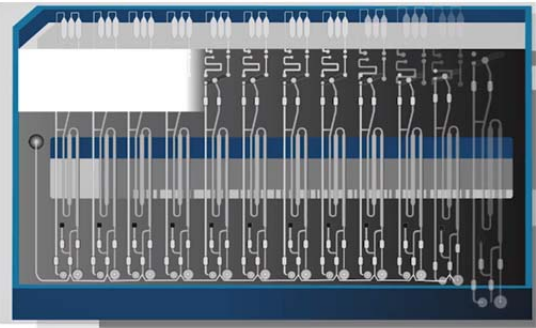
Claim	Claim Language	Infringement Evidence
		<p>of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160. DNA was eluted into 10 uL of ELU-2 and 2 uL of the eluate was used for real-time PCR in an example of Step S110.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 21:42-48 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 22:5-11 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 22:67-23:6 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 23:42-48 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 or ELU-3 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 30:62-63 (“ELUTION SOLUTION ELU-3 40 mM KOH: ultrapure water (960 mL) and 1N KOH (40 mL).”) • U.S. Patent No. 9,540,636 at col. 23:23-29 (“Upon removal of the unbound Supernatant in an example of Step S140, the PAA affinity moieties coated onto magnetic microparticles were washed twice (2x) with 500 uL of WSH-1 solution in an example of Step S150, and then the captured RNA and DNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”)

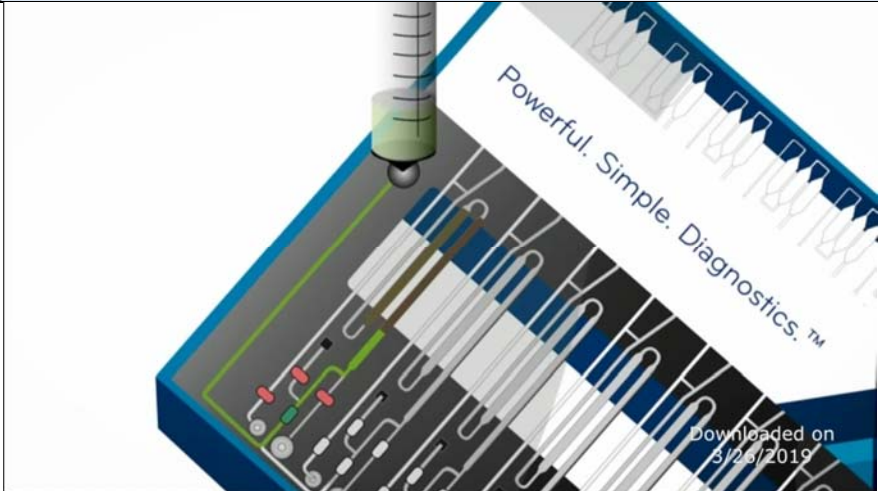
Claim	Claim Language	Infringement Evidence
		<p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> • Claim 15. The method of claim 1, wherein releasing the nucleic acid sample from the set of moiety-bound nucleic acid particles comprises contacting the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH that is in the range of pH 10 to pH 13. • Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the microfluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20 uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction.

Claim	Claim Language	Infringement Evidence
		 <p data-bbox="1108 699 1283 732">FIGURE 1C</p> <ul data-bbox="682 755 1984 1411" style="list-style-type: none"> • U.S. Patent No. 9,382,532 at col. 9:9-24 (“In one variation of Step S160, the affinity moieties, examples of which are described in Section 2 below, function based upon the pH of the environment. Specifically, at low pH, the affinity moieties are positively charged, which results in attraction to negatively charged nucleic acids; however, at high pH, the affinity moieties are negatively charged, which results in repulsion of negatively charged nucleic acids. In a specific example of this variation, releasing the nucleic acid sample comprises providing an elution solution that is in the range of pH 12-pH 13 to effect efficient elution/release of the bound target nucleic acid(s) from the microparticle based upon a shift to a more basic pH. In the specific example, the elution solution comprises 20 mM of NaOH: however, in other variations the elution Solution can comprise any other suitable concentration of NaOH or KOH, depending upon the application (e.g., sample type).”) • U.S. Patent No. 9,382,532 at col. 14:54-61 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL or 250 uL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160. RNA was eluted into 10 uL of ELU-2 and 8 uL of the eluate was used for real-time RT-PCR in an example of Step 170.”) • U.S. Patent No. 9,382,532 at col. 28:64-65 (“Elution Solution ELU-2 - 40 mM NaOH: ultrapure

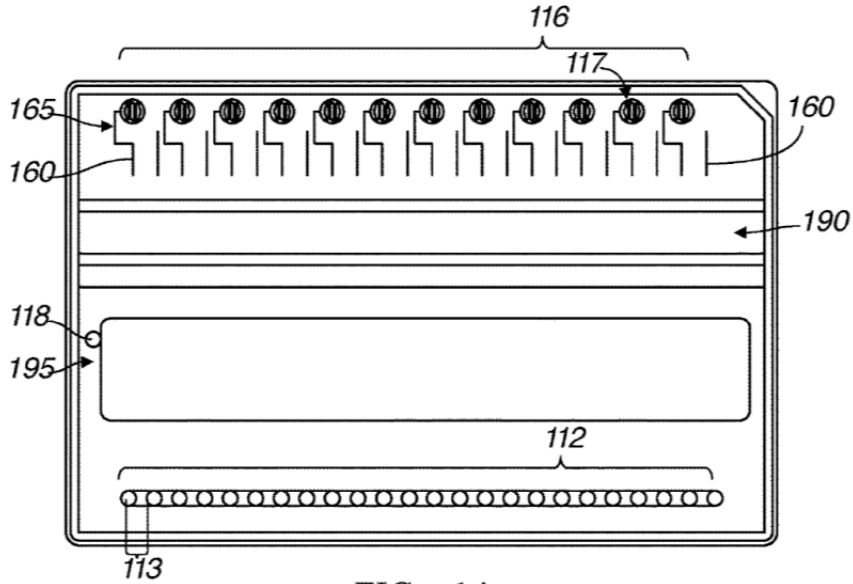
Claim	Claim Language	Infringement Evidence
		<p>water (960 mL) and 1N NaOH (40 mL).”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at 15:19-26 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160. RNA was eluted into 10 uL of ELU-2 and 2 LL of the eluate was used for real-time RT-PCR in an example of Step S170.”) • U.S. Patent No. 9,382,532 at 16:6-14 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-1 and heating the microparticles to 85 C for 3 minutes in an example of Step S160. DNA was eluted into 10 uL of ELU-1 and 8 ul of the eluate was used for real-time PCR in an example of Step S170.”) • U.S. Patent No. 9,382,532 at 28:62-63 (“Elution Solution ELU-1 - 20 mM NaOH: ultrapure water (980 mL) and 1N NaOH (20 mL). • U.S. Patent No. 9,382,532 at 16:38-44 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500LL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at 17:4-10 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the magnetic microparticles to 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at 17:37-43 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at col. 18:8-16 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of

Claim	Claim Language	Infringement Evidence
		<p>WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160. DNA was eluted into 10 uL of ELU-2 and 2 ul of the eluate was used for real-time PCR in an example of Step S170.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at col. 18:41-47 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed twice with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at 19:22-27 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at 19:56-61 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500LL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at 20:17-23 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at col. 21:34-39 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500LL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at col. 22:2-8 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 or ELU-3 and heating the microparticles to 85C for 3 minutes in an example of Step S160.”)

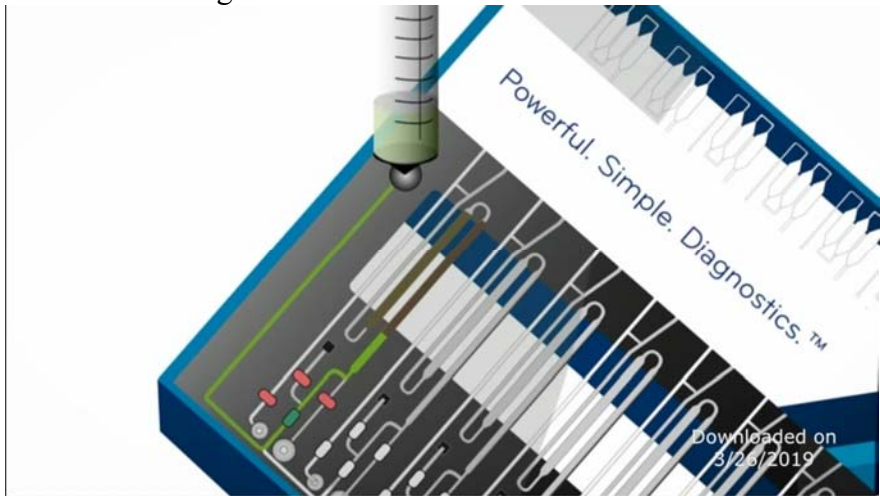
Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> U.S. Patent No. 9,382,532 at col. 28:667-67 (“Elution Solution ELU-3-40 mM KOH: ultrapure water (960 mL) and 1N KOH (40 mL).”)
1(r)	wherein the microfluidic network further comprises an inlet for receiving the release solution into the microfluidic network and one or more channels leading from the inlet to the first processing region	<p>The accused system comprises the microfluidic network further comprising an inlet for receiving the release solution into the microfluidic network and one or more channels leading from the inlet to the first processing region.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59  <ul style="list-style-type: none"> “A high pH NeuMoDx release reagent is dispensed into the s-channel to cover the beads and heat is applied to complete the denaturation process, resulting in released nucleic acid or eluent.” 2:55-58 2:58 Release reagent

Claim	Claim Language	Infringement Evidence
		 <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and

Claim	Claim Language	Infringement Evidence
		<p>releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 13: The method of claim 3, wherein releasing the nucleic acid sample from the set of moiety-bound nucleic acid particles comprises occluding the fluidic pathway of the cartridge, comprising the process chamber, at a set of occlusion positions, upon displacement of pins of the set of pins, to define a path through a magnetic field; delivering the set of moiety-bound nucleic acid particles into the path of the fluidic pathway; and delivering an elution solution into the fluidic pathway, thereby inducing a pH shift configured to release the nucleic acid sample from the set of moiety-bound nucleic acid particles.” • Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the microfluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20 uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction. <p>US9738887 (Exhibit 31)</p>

Claim	Claim Language	Infringement Evidence
		 <p style="text-align: center;"><u>FIG. 1A</u></p>

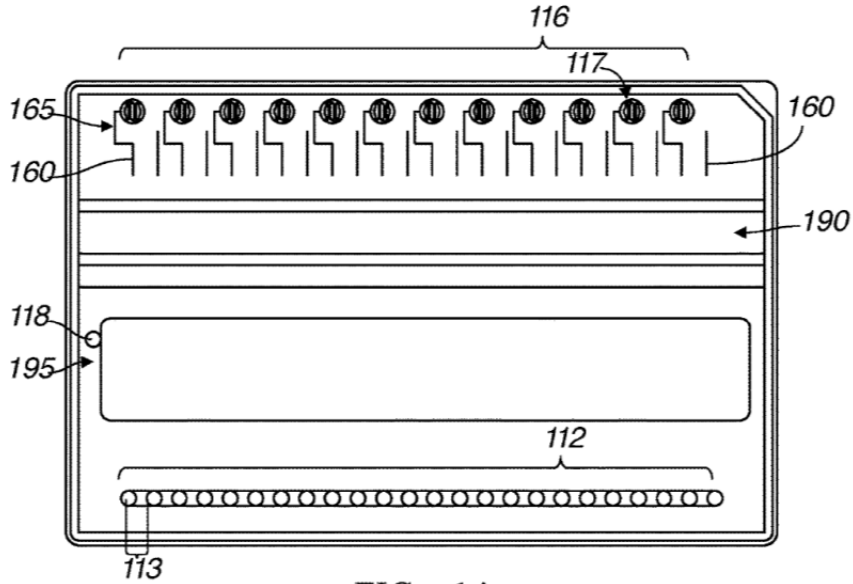
Claim	Claim Language	Infringement Evidence
		<div data-bbox="758 240 1541 526"> <p style="text-align: center;">FIG. 1J</p> </div> <div data-bbox="758 542 1541 818"> <p style="text-align: center;">FIG. 1K</p> <p style="text-align: right;">○ OCCLUDED</p> </div> <ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at 13:35-42 (“The set of fluidic pathways 160 of the microfluidic cartridge 100 functions to provide a fluid network into which volumes of sample fluids, reagents, buffers and/or gases used in a molecular diagnostics protocol may be delivered, out of which waste fluids may be eliminated, and by which processed nucleic acid samples may be delivered to a detection chamber for analysis, which may include amplification and/or detection.”) U.S. Patent No. 9,738,887 at 15:15-28 (“The capture segment 166 functions to facilitate isolation and purification of nucleic acids from the volume of the sample fluid, and may be s-shaped and/or progressively narrowing, to increase the efficiency and/or effectiveness of isolation and purification. Alternatively, the capture segment 166 may altogether be replaced by a substantially straight portion 166 or any other geometric shape or configuration that functions to facilitate isolation and purification of nucleic acids from the volume of the sample fluid. The capture segment 166 of the fluidic pathway 165 preferably has an aspect ratio less than one, which functions to facilitate capture of magnetic particles, but may alternatively have an aspect ratio that is not less than one.”)

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at 16:58-65 (“Thereafter in the first embodiment, as shown in FIG. 1E, the fluidic pathway 165 may be occluded at the second occlusion position 143 and the occlusion at the first occlusion 142 may be reversed, thus creating a third truncated pathway as shown in FIG. 1D. A release solution may then be delivered through the fluid port 118, into the capture segment 166, and to the waste chamber 130 by passing the fifth occlusion position 146.”)
1(s)	wherein the first processing region is configured to receive the release solution therein, and	<p>The accused system comprises the first processing region configured to receive the release solution therein.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMoDx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “A high pH NeuMoDx release reagent is dispensed into the s-channel to cover the beads and heat is applied to complete the denaturation process, resulting in released nucleic acid or eluent.” 2:55-58 2:58 Release reagent 

Claim	Claim Language	Infringement Evidence
		<p>40600146_D-IFU-NeuMoDx-LDT-Master-Mix-RNA-US-ONLY (Exhibit 62)</p> <ul style="list-style-type: none"> “NeuMoDxTM LDT Master Mix, RNA Instructions for Use...Upon lysis, the released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are then loaded into the NeuMoDxTM Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDxTM WASH Solution and the bound RNA is eluted using NeuMoDxTM RELEASE Solution.” <p>40600145_-Rev-D-IFU-NeuMoD-LDT-Master-Mix-DNA-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 67)</p> <ul style="list-style-type: none"> “NeuMoDxTM LDT Master Mix, DNA Instructions for Use...Upon lysis, the released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are then loaded into the NeuMoDxTM Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDxTM WASH Solution and the bound DNA is eluted using NeuMoDxTM RELEASE Solution.” <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> “NeuMoDxTM Cartridge Instructions for Use...The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDxTM WASH Solution and the bound nucleic acid is eluted using the NeuMoDxTM RELEASE Solution.” <p>40600129_D-IFU-GBS-Test-Strip-US-only.pdf (Exhibit 60)</p> <ul style="list-style-type: none"> “NeuMoDxTM GBS Test Strip Instructions for Use...The released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are loaded in to the NeuMoDxTM Cartridge where the unbound, non-DNA components are further washed away with NeuMoDxTM WASH Solution and the bound DNA is eluted using NeuMoDxTM RELEASE Solution.” <p>40600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018 (Exhibit 20)</p> <ul style="list-style-type: none"> “NeuMoDxTM Release Reagent Instructions for Use...NeuMoDxTM Release Reagent is a proprietary reagent that releases captured nucleic acid from NeuMoDxTM proprietary


Claim	Claim Language	Infringement Evidence
		<p>affinity magnetic microspheres providing the eluate at the proper pH for mixing the dried reagents in a NeuMoDx™ test strip and subsequent Real-Time PCR.”</p> <p>US9433940 (Exhibit 57)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,433,940 at Abstract (“A microfluidic cartridge, configured to facilitate processing and detection of nucleic acids, comprising: a top layer comprising a set of cartridge-aligning indentations, a set of sample port-reagent port pairs, a shared fluid port, a vent region, a heating region, and a set of detection chambers; an intermediate Substrate, coupled to the top layer comprising a waste chamber; an elastomeric layer, partially situated on the intermediate substrate; and a set of fluidic pathways, each formed by at least a portion of the top layer and a portion of the elastomeric layer, wherein each fluidic path way is fluidically coupled to a sample port-reagent port pair, the shared fluid port, and a Detection chamber, comprises a turnabout portion passing through the heating region, and is configured to be occluded upon deformation of the elastomeric layer, to transfer a waste fluid to the waste chamber, and to pass through the vent region.”) • U.S. Patent No. 9,433,940 at col. 16:65-17:3 (“The release solution may then be sealed within a fourth truncated pathway (including the capture segment 166) of the fluidic pathway 165 by occluding the fluidic pathway at the fifth occlusion position 146, as shown in FIG. 1F. A release solution may then be delivered to other fluidic pathways of the set of fluidic pathways 160.”) • U.S. Patent No. 9,443,940 at col. 17:4-26 (“Thereafter, as shown in FIG. 1G, the occlusion at the fourth occlusion position 145 may be reversed, creating a fifth truncated pathway, and release solution within the fluidic pathway 165 may be metered by pumping air through the fluid port 118, which functions to push a portion of the release solution into the waste chamber 130. A volume of release solution will still be maintained within the capture segment 166 at this stage. As shown in FIG. 1H, the first and the fourth occlusion positions 142, 145 may then be occluded to form a sixth truncated pathway sealing the volume of release solution, with the captured magnetic beads bound to nucleic acids, within the capture segment 166. The volume of the remaining release solution is therefore substantially defined by the microchannel volume between junctions in the fluidic pathway 165 near the fourth and sixth occlusion positions 145, 147, and may be any small volume but in a specific variation is precisely metered to be 23+/- 1 microliters.

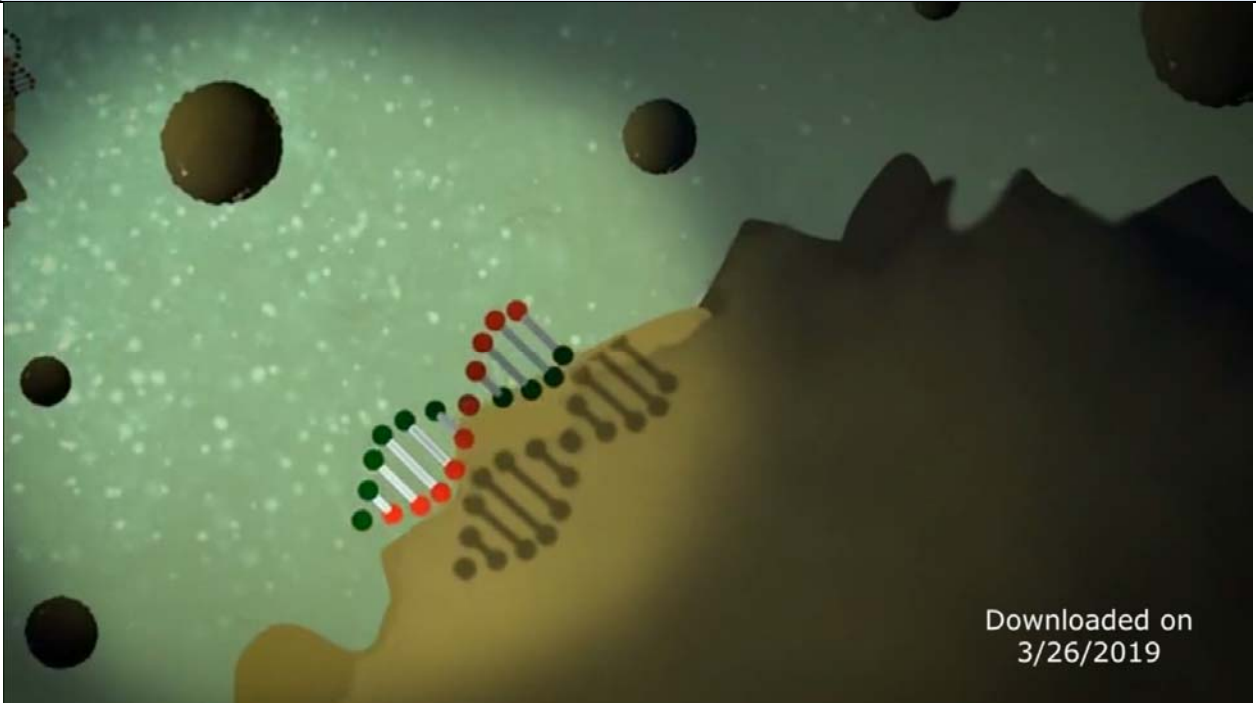
Claim	Claim Language	Infringement Evidence
		<p>Release solution may be sealed within capture segments of other fluidic pathways using a similar process. A heater may then be provided at the sixth truncated pathway, inducing a pH shift within the sixth truncated pathway to unbind nucleic acids from the magnetic beads.”)</p> <p>US9452430 (Exhibit 56)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,452,430 at col. 17:9-31 (“Thereafter, as shown in FIG. 1G, the occlusion at the fourth occlusion position 145 may be reversed, creating a fifth truncated pathway, and release solution within the fluidic pathway 165 may be metered by pumping air through the fluid port 118, which functions to push a portion of the release solution into the waste chamber 130. A volume of release solution will still be maintained within the capture segment 166 at this stage. As shown in FIG. 1H, the first and the fourth occlusion positions 142, 145 may then be occluded to form a sixth truncated pathway sealing the volume of release solution, with the captured magnetic beads bound to nucleic acids, within the capture segment 166. The volume of the remaining release solution is therefore substantially defined by the microchannel volume between junctions in the fluidic pathway 165 near the fourth and sixth occlusion positions 145, 147, and may be any small volume but in a specific variation is precisely metered to be 23+/- 1 microliters. Release solution may be sealed within capture segments of other fluidic pathways using a similar process. A heater may then be provided at the sixth truncated pathway, inducing a pH shift within the sixth truncated pathway to unbind nucleic acids from the magnetic beads.”) <p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at 3:52-59 (“Each sample-port reagent port pair 113 of an embodiment of the top layer 110 also comprises a reagent port 115, as shown in FIG. 1A. The reagent port 115 in a sample port-reagent port pair 113 functions to receive a volume of fluid comprising a reagent used in molecular diagnostics, for delivery of the volume of fluid comprising a reagent to a portion of a fluidic pathway 165 coupled to the sample port-reagent port pair 113.”)

Claim	Claim Language	Infringement Evidence
		 <p style="text-align: center;"><u>FIG. 1A</u></p>

Claim	Claim Language	Infringement Evidence
		<div data-bbox="756 240 1543 527"> <p style="text-align: center;">FIG. 1J</p> </div> <div data-bbox="756 544 1543 828"> <p style="text-align: center;">FIG. 1K</p> <p style="text-align: right;">○ OCCLUDED</p> </div> <ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at 13:35-42 (“The set of fluidic pathways 160 of the microfluidic cartridge 100 functions to provide a fluid network into which volumes of sample fluids, reagents, buffers and/or gases used in a molecular diagnostics protocol may be delivered, out of which waste fluids may be eliminated, and by which processed nucleic acid samples may be delivered to a detection chamber for analysis, which may include amplification and/or detection.”) U.S. Patent No. 9,738,887 at 15:15-28 (“The capture segment 166 functions to facilitate isolation and purification of nucleic acids from the volume of the sample fluid, and may be s-shaped and/or progressively narrowing, to increase the efficiency and/or effectiveness of isolation and purification. Alternatively, the capture segment 166 may altogether be replaced by a substantially straight portion 166 or any other geometric shape or configuration that functions to facilitate isolation and purification of nucleic acids from the volume of the sample fluid. The capture segment 166 of the fluidic pathway 165 preferably has an aspect ratio less than one, which functions to facilitate capture of magnetic particles, but may alternatively have an aspect ratio that is not less than one.”)

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at 16:58-65 (“Thereafter in the first embodiment, as shown in FIG. 1E, the fluidic pathway 165 may be occluded at the second occlusion position 143 and the occlusion at the first occlusion 142 may be reversed, thus creating a third truncated pathway as shown in FIG. 1D. A release solution may then be delivered through the fluid port 118, into the capture segment 166, and to the waste chamber 130 by passing the fifth occlusion position 146.”) <p>US9540636 (Exhibit 54)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,540,636 at col. 27:4-17 (“Thereafter in the first illustration, as shown in FIG. 22C, the fluidic pathway 165 may be occluded at the second occlusion position 143 and the occlusion at the first occlusion 142 may be reversed, thus creating a third truncated pathway as shown in FIG. 22B. A release solution may then be delivered through the fluid port 118, into the capture segment 166, and to the waste chamber 130 by passing the fifth occlusion position 146. The release solution may then be sealed within a fourth truncated pathway (including the capture segment 166) of the fluidic pathway 165 by occluding the fluidic pathway at the fifth occlusion position 146. A release solution may then be delivered to other fluidic pathways of the set of fluidic pathways 160.”)
1(t)	wherein, in the presence of the release solution in the first processing region, the plurality of magnetic binding particles are configured to release at least a portion of the polynucleotides into an eluate solution in the first processing region	<p>The accused system comprises, in the presence of the release solution in the first processing region, the plurality of magnetic binding particles are configured to release at least a portion of the polynucleotides into an eluate solution in the first processing region.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMoDx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “A high pH NeuMoDx release reagent is dispensed into the s-channel to cover the beads and heat is applied to complete the denaturation process, resulting in released nucleic acid or eluent.” 2:55-58 2:58 Release reagent

Claim	Claim Language	Infringement Evidence
		<div></div> <ul style="list-style-type: none">• 3:04 Heat/denaturation

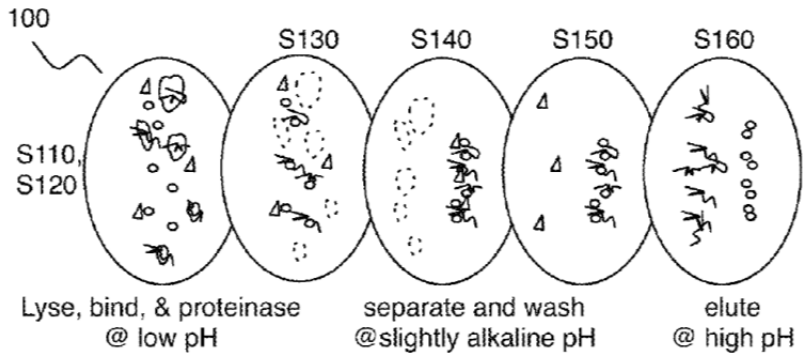
Claim	Claim Language	Infringement Evidence
		 <p data-bbox="634 1003 1640 1036">40600146_D-IFU-NeuMoDx-LDT-Master-Mix-RNA-US-ONLY (Exhibit 62)</p> <ul data-bbox="688 1040 1980 1219" style="list-style-type: none"> • “NeuMoDx™ LDT Master Mix, RNA Instructions for Use...Upon lysis, the released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound RNA is eluted using NeuMoDx™ RELEASE Solution.” <p data-bbox="634 1263 1955 1328">40600145_-Rev-D-IFU-NeuMoD-LDT-Master-Mix-DNA-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 67)</p> <ul data-bbox="688 1333 1980 1404" style="list-style-type: none"> • “NeuMoDx™ LDT Master Mix, DNA Instructions for Use...Upon lysis, the released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bund nucleic

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		<p>acids, are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH SOLUTION and the bound DNA is eluted using NeuMoDx™ RELEASE Solution.”</p> <p>40600094_D-IFU-NeuMoDx-Cartidge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> • “NeuMoDx™ Cartridge Instructions for Use...The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound nucleic acid is eluted using the NeuMoDx™ RELEASE Solution.” <p>40600129_D-IFU-GBS-Test-Strip-US-only.pdf (Exhibit 60)</p> <ul style="list-style-type: none"> • “NeuMoDx™ GBS Test Strip Instructions for Use...The released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are loaded in to the NeuMoDx™ Cartridge where the unbound, non-DNA components are further washed away with NeuMoDx™ WASH Solution and the bound DNA is eluted using NeuMoDx™ RELEASE Solution.” <p>40600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018 (Exhibit 20)</p> <ul style="list-style-type: none"> • “NeuMoDx™ Release Reagent Instructions for Use...NeuMoDx™ Release Reagent is a proprietary reagent that releases captured nucleic acid from NeuMoDx™ proprietary affinity magnetic microspheres providing the eluate at the proper pH for mixing the dried reagents in a NeuMoDx™ test strip and subsequent Real-Time PCR.” <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator

Claim	Claim Language	Infringement Evidence
		<p>allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • U.S. Patent 9,050,594 at col. 29:57-30: (“Step S444 functions to wash at least one nucleic acid-magnetic bead sample in the set of nucleic acid-magnetic bead samples, and Step S445 functions to release at least one nucleic acid volume from the set of nucleic acid-magnetic bead samples. The heater provided in Step S442 may be activated after Step S445 to induce a pH shift.”) <p>US9339812 (Exhibit 26)</p> <ul style="list-style-type: none"> • Claim 7. The method of claim 6, wherein separating the volume of nucleic acids from the biological sample further comprises dispensing a release solution through the fluidic pathway by the fluid port. • Claim 8. The method of claim 7, wherein separating the volume of nucleic acids from the biological sample further comprises heating the first portion of the fluidic pathway to facilitate a pH shift, thus releasing nucleic acids from magnetic beads to produce the volume of nucleic acids. • Claim 20. The method of claim 19, wherein producing the set of nucleic acid volumes from the set of nucleic acid-magnetic bead samples comprises: upon passing a magnet through one of the set of slots of the cartridge platform of the molecular diagnostic module, providing a magnetic field spanning a portion of each fluidic pathway in the set of fluidic pathways, thus capturing the set of nucleic acid-magnetic bead samples; dispensing a wash solution into each fluidic pathway of the set of fluidic pathways; dispensing a release solution into each fluidic pathway of the set of fluidic pathways; and heating each fluidic pathway of the set of fluidic pathways to facilitate a pH shift, thus unbinding nucleic acids from magnetic beads to produce the set of nucleic acid volumes. • U.S. Patent No. 9,339,812 at col. 10:49-52 (“The cartridge heater functions to transfer heat to a heating region of a microfluidic cartridge, for inducing a pH shift to release bound nucleic acids from magnetic beads within the heating region.”) • U.S. Patent NO. 9,339,812 at col. 25:43-49 (“The syringe pump 265 of the liquid handling

Claim	Claim Language	Infringement Evidence
		<p>system 250 is coupled to a wash solution source 266, a release solution source 267, a source of air 268, and flexible tubing 291, and functions to deliver a wash solution, a release solution, and air through a valve to the molecular diagnostic module 130 to facilitate isolation and purification of nucleic acids from a set of magnetic bead-samples.”)</p> <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> • Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10. • Claim 12. The method of claim 1, further comprising releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles, wherein releasing the nucleic acid sample comprises contacting the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH that is greater than pH 10. • Claim 13: The method of claim 3, wherein releasing the nucleic acid sample from the set of moiety-bound nucleic acid particles comprises occluding the fluidic pathway of the cartridge, comprising the process chamber, at a set of occlusion positions, upon displacement of pins of the set of pins, to define a path through a magnetic field; delivering the set of moiety-bound nucleic

Claim	Claim Language	Infringement Evidence
		<p>acid particles into the path of the fluidic pathway; and delivering an elution solution into the fluidic pathway, thereby inducing a pH shift configured to release the nucleic acid sample from the set of moiety-bound nucleic acid particles.”</p> <ul style="list-style-type: none"> • Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the microfluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20 uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction.

Claim	Claim Language	Infringement Evidence
		 <p data-bbox="1081 667 1247 699">FIGURE 1C</p> <ul data-bbox="688 721 1982 1412" style="list-style-type: none"> <li data-bbox="688 721 1982 1268">• U.S. Patent No. 9,382,532 at 9:9-30 (“In one variation of Step S160, the affinity moieties, examples of which are described in Section 2 below, function based upon the pH of the environment. Specifically, at low pH, the affinity moieties are positively charged, which results in attraction to negatively charged nucleic acids; however, at high pH, the affinity moieties are negatively charged, which results in repulsion of negatively charged nucleic acids. In a specific example of this variation, releasing the nucleic acid sample comprises providing an elution solution that is in the range of pH 12-pH 13 to effect efficient elution/release of the bound target nucleic acid(s) from the microparticle based upon a shift to a more basic pH. In the specific example, the elution solution comprises 20 mM of NaOH; however, in other variations the elution solution can comprise any other suitable concentration of NaOH or KOH, depending upon the application (e.g., sample type). Again, substantial removal of the wash solution during variations of the method 100 comprising Step S150 can facilitate or enhance the pH-shift for nucleic acid release, as the wash solution can potentially neutralize the elution solution in an undesirable manner and mitigate the elevated pH necessary for releasing the target nucleic acid(s).”) <li data-bbox="688 1273 1982 1412">• U.S. Patent No. 9,382,532 at 11:30-40 (“Nucleic acid molecules are typically negatively charged at standard processing conditions. In such processes, positively charged moieties can capture and retain the negatively charged nucleic acid molecules; however, the positively charged moieties can bind too strongly with target nucleic acids leading to an irreversible process

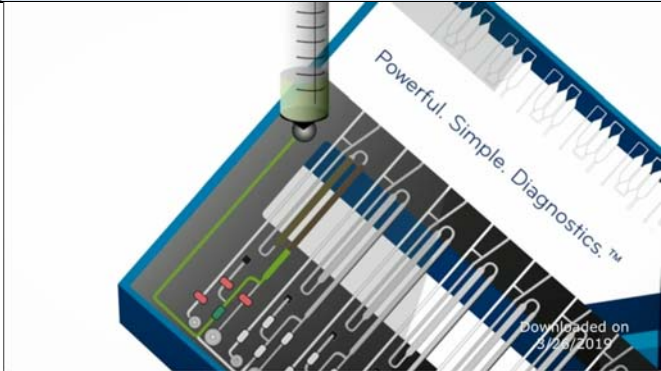
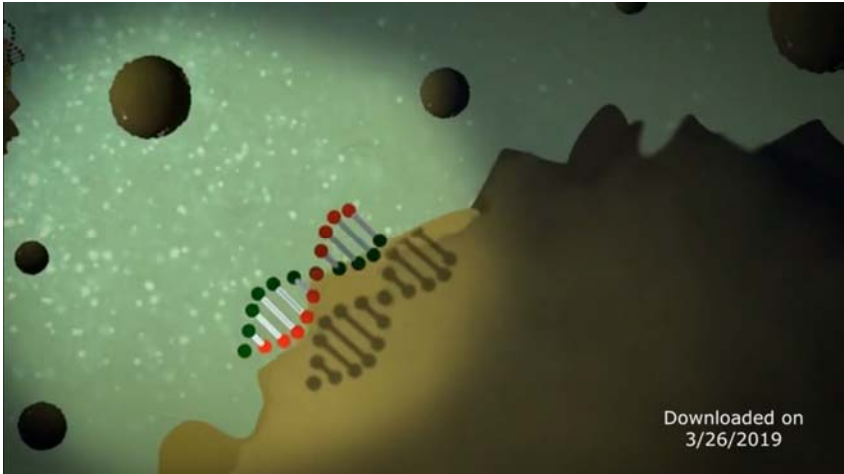
Claim	Claim Language	Infringement Evidence
		<p>whereby the bound nucleic acid cannot be released into the solution for further processing/analysis. Two novel molecules that are capable of binding nucleic acid in a reversible manner are described below, wherein the reversible binding is modulated by changing the pH of the environment.”)</p> <p>US9540636 (Exhibit 54)</p> <ul style="list-style-type: none"> • Claim 17: A method for nucleic acid isolation from a biological sample, comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution includes a set of affinity moiety-coated microparticles; producing a moiety-sample mixture upon combination of the binding moiety solution with the biological sample; producing a set of moiety-bound nucleic acid particles upon incubation of the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles; occluding a fluidic pathway of a cartridge upon displacement of a first subset of pin at the cartridge comprising the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles, within the fluidic pathway of the cartridge; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution. • Claim 12. The method of claim 1, further comprising releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles, wherein releasing the nucleic acid sample comprises contacting the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH that is greater than pH 10. • Claim 17: A method for nucleic acid isolation from a biological sample, comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution includes a set of affinity moiety-coated microparticles; producing a moiety-sample mixture upon combination of the binding moiety solution with the biological sample; producing a set of moiety-bound nucleic acid particles upon incubation of the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles; occluding a fluidic pathway of a cartridge upon displacement of a first subset of pin at the cartridge comprising the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles, within the fluidic pathway of the cartridge; and

Claim	Claim Language	Infringement Evidence
		<p>releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution.</p> <ul style="list-style-type: none"> U.S. Patent No. 9,382,532 at col. 9:9-24 (“In one variation of Step S160, the affinity moieties, examples of which are described in Section 2 below, function based upon the pH of the environment. Specifically, at low pH, the affinity moieties are positively charged, which results in attraction to negatively charged nucleic acids; however, at high pH, the affinity moieties are negatively charged, which results in repulsion of negatively charged nucleic acids. In a specific example of this variation, releasing the nucleic acid sample comprises providing an elution solution that is in the range of pH 12-pH 13 to effect efficient elution/release of the bound target nucleic acid(s) from the microparticle based upon a shift to a more basic pH. In the specific example, the elution solution comprises 20 mM of NaOH; however, in other variations the elution Solution can comprise any other suitable concentration of NaOH or KOH, depending upon the application (e.g., sample type).”) U.S. Patent No. 9,540,636 at col. 9:34-42 (“In a specific example of this variation, releasing the nucleic acid sample comprises providing an elution solution that is in the range of pH 12-pH 13 to effect efficient elution/release of the bound target nucleic acid(s) from the microparticle based upon a shift to a more basic pH. In the specific example, the elution solution comprises 20 mM of NaOH; however, in other variations the elution solution can comprise any other suitable concentration of NaOH or KOH, depending upon the application (e.g., sample type).”) U.S. Patent No. 9,540,636 at col.14:22-28 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 500 uL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) U.S. Patent No. 9,540,636 at col. 30:60-61 (“ELUTION SOLUTION ELU-2 40 mM NaOH: ultrapure water (960 mL) and 1N NaOH (40 mL).”) U.S. Patent No. 9,540,636 at col. 14:57-63 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 250 uL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) U.S. Patent No. 9,540,636 at col. 15:31-36 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL or 250 uL of WSH-1 solution in an example of Step S150 and the captured RNA

Claim	Claim Language	Infringement Evidence
		<p>was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 15:67-16:6 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 16:58-64 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-1 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 30:58-59 (“ELUTION SOLUTION ELU-1 20 mM NaOH: ultrapure water (980 mL) and 1N NaOH (20 mL).”) • U.S. Patent No. 9,540,636 at col. 17:29-34 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 17:66-18:5 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the magnetic microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 18:37-43 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 19:13-19 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an

Claim	Claim Language	Infringement Evidence
		<p>example of Step S160.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 19:51-57 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed twice with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 20:37-43 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 21:9-16 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160. DNA was eluted into 10 uL of ELU-2 and 2 uL of the eluate was used for real-time PCR in an example of Step S110.”) • U.S. Patent No. 9,540,636 at col. 21:42-48 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 22:5-11 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 22:67-23:6 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 23:42-48 (“Upon removal of the unbound supernatant in an

Claim	Claim Language	Infringement Evidence
		<p>example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 or ELU-3 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.")</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 30:62-63 ("ELUTION SOLUTION ELU-3 40 mM KOH: ultrapure water (960 mL) and 1N KOH (40 mL).") • U.S. Patent No. 9,540,636 at col. 24:23-29 ("Upon removal of the unbound Supernatant in an example of Step S140, the PAA affinity moieties coated onto magnetic microparticles were washed twice (2x) with 500 uL of WSH-1 solution in an example of Step S150, and then the captured RNA and DNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.") <p>US10010888 (Exhibit 55)</p> <ul style="list-style-type: none"> • Claim 17. The method of claim 14, further comprising delivering a release solution into the fluidic pathway, thereby producing a nucleic acid volume from the nucleic acid-magnetic bead sample. • U.S. Patent No. 10,010,888 at col. 34:4-11 ("Step S442 functions to provide a heater, which, in combination with a release solution that provides a pH shift, facilitates a rapid and efficient unbinding of the nucleic acids from the magnetic beads.")
1(u)	wherein the first heat source is configured to apply heat to the lysate solution and the plurality of magnetic binding particles in the first processing region, and	<p>The accused system comprises the first heat source configured to apply heat to the lysate solution and the plurality of magnetic binding particles in the first processing region.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMoDx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to "VIDEO NeuMoDx™ WORKFLOW" hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • "A high pH NeuMoDx release reagent is dispensed into the s-channel to cover the beads and heat is applied to complete the denaturation process, resulting in released nucleic acid or eluent." 2:55-3:10 • 2:58 Release reagent

Claim	Claim Language	Infringement Evidence
		<div data-bbox="732 228 1388 597">  </div> <ul style="list-style-type: none"> <li data-bbox="688 602 1029 634">• 3:04 Heat/denaturation <div data-bbox="732 634 1570 1105">  </div> <p data-bbox="638 1182 955 1214">US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> <li data-bbox="688 1222 1984 1398">• Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module

Claim	Claim Language	Infringement Evidence
		<p>comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at col. 10:49-52 (“The cartridge heater 153 functions to transfer heat to a heating region 224 of a microfluidic cartridge 210, for inducing a pH shift to release bound nucleic acids from magnetic beads within the heating region 224.”) • U.S. Patent 9,050,594 at col. 30:1:7 (“Step S444 functions to wash at least one nucleic acid-magnetic bead sample in the set of nucleic acid-magnetic bead samples, and Step S445 functions to release at least one nucleic acid volume from the set of nucleic acid-magnetic bead samples. The heater provided in Step S442 may be activated after Step S445 to induce a pH shift.”) <p>US9339812 (Exhibit 26)</p> <ul style="list-style-type: none"> • Claim 7. The method of claim 6, wherein separating the volume of nucleic acids from the biological sample further comprises dispensing a release solution through the fluidic pathway by the fluid port. • Claim 8. The method of claim 7, wherein separating the volume of nucleic acids from the biological sample further comprises heating the first portion of the fluidic pathway to facilitate a pH shift, thus releasing nucleic acids from magnetic beads to produce the volume of nucleic acids. • Claim 20. The method of claim 19, wherein producing the set of nucleic acid volumes from the set of nucleic acid-magnetic bead samples comprises: upon passing a magnet through one of the set of slots of the cartridge platform of the molecular diagnostic module, providing a magnetic field spanning a portion of each fluidic pathway in the set of fluidic pathways, thus capturing the set of nucleic acid-magnetic bead samples; dispensing a wash solution into each fluidic pathway of the set of fluidic pathways; dispensing a release solution into each fluidic pathway of the set of fluidic pathways; and heating each fluidic pathway of the set of fluidic pathways to facilitate a pH shift, thus unbinding nucleic acids from magnetic beads to produce the set of

Claim	Claim Language	Infringement Evidence
		<p>nucleic acid volumes.</p> <ul style="list-style-type: none"> U.S. Patent No. 9,339,812 at col. 10:49-52 (“The cartridge heater functions to transfer heat to a heating region of a microfluidic cartridge, for inducing a pH shift to release bound nucleic acids from magnetic beads within the heating region.”) U.S. Patent No. 9,339,812 at col. 29:50-53 (“Step S442 functions to provide a heater, which, in combination with a release solution that provides a pH shift, facilitate a rapid and efficient unbinding of the nucleic acids from magnetic beads.”) <p>US9540636 (Exhibit 54)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,540,636 at col. 10:3-14 (“In an example of Step S161, heating comprises elevating the temperature of the moiety-bound nucleic acid volume to 80-85 C, for 3 minutes, and in another example, heating comprises elevating the temperature of the moiety-bound nucleic acid volume to 50-70 C, for 3-10 minutes.”) U.S. Patent No. 9,540,636 at col. 14:22-28 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 500 uL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) U.S. Patent No. 9,540,636 at col. 30:60-61 (“ELUTION SOLUTION ELU-2 40 mM NaOH: ultrapure water (960 mL) and 1N NaOH (40 mL).”) U.S. Patent No. 9,540,636 at col. 14:57-63 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 250 uL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) U.S. Patent No. 9,540,636 at col. 15:31-36 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL or 250 uL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”) U.S. Patent No. 9,540,636 at col.15:67-16:6 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”)

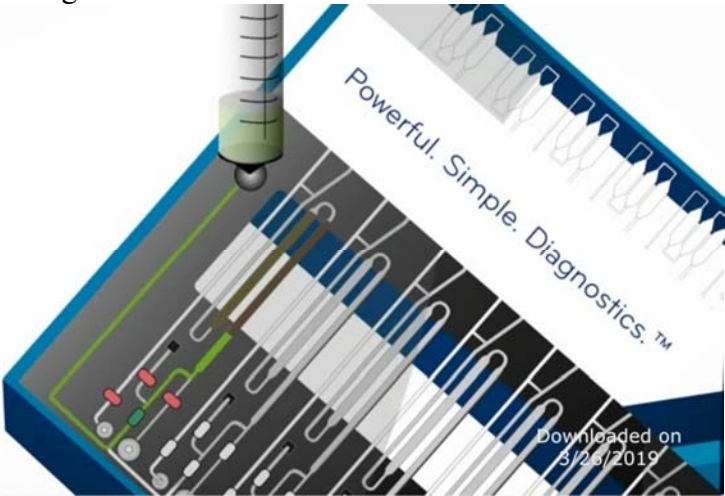
Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 16:57-64 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-1 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 30:58-59 (“ELUTION SOLUTION ELU-1 20 mM NaOH: ultrapure water (980 mL) and 1N NaOH (20 mL).”) • U.S. Patent No. 9,540,636 at col. 17:29-34 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 17:66-18:5 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the magnetic microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 18:37-43 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 19:13-19 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 19:51-57 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed twice with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”)

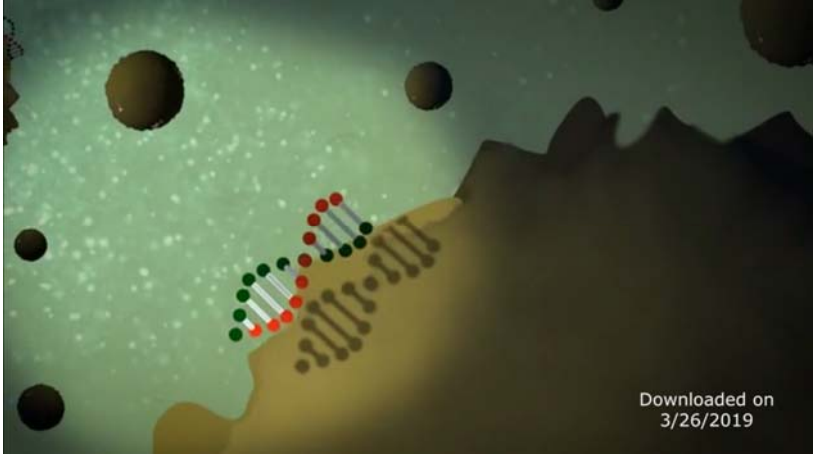
Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 20:37-43 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 21:9-16 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160. DNA was eluted into 10 uL of ELU-2 and 2 uL of the eluate was used for real-time PCR in an example of Step S110.”) • U.S. Patent No. 9,540,636 at col. 21:42-48 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 22:5-11 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 22:67-23:6 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 23:42-48 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 or ELU-3 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 30:62-63 (“ELUTION SOLUTION ELU-3 40 mM KOH: ultrapure water (960 mL) and 1N KOH (40 mL).”)

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> U.S. Patent No. 9,540,636 at col. 24:23-29 (“Upon removal of the unbound Supernatant in an example of Step S140, the PAA affinity moieties coated onto magnetic microparticles were washed twice (2x) with 500 uL of WSH-1 solution in an example of Step S150, and then the captured RNA and DNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”) <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,382,532 at col. 14:54-61 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL or 250 uL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160. RNA was eluted into 10 uL of ELU-2 and 8 uL of the eluate was used for real-time RT-PCR in an example of Step 170.”) U.S. Patent No. 9,382,532 at col. 28:64-65 (“Elution Solution ELU-2 - 40 mM NaOH: ultrapure water (960 mL) and 1N NaOH (40 mL).”) U.S. Patent No. 9,382,532 at 15:19-26 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160. RNA was eluted into 10 uL of ELU-2 and 2 LL of the eluate was used for real-time RT-PCR in an example of Step S170.”) U.S. Patent No. 9,382,532 at 16:6-14 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-1 and heating the microparticles to 85 C for 3 minutes in an example of Step S160. DNA was eluted into 10 uL of ELU-1 and 8 ul of the eluate was used for real-time PCR in an example of Step S170.”) U.S. Patent No. 9,382,532 at 28:62-63 (“Elution Solution ELU-1 - 20 mM NaOH: ultrapure water (980 mL) and 1N NaOH (20 mL).”) U.S. Patent No. 9,382,532 at 16:38-44 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500LL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix

Claim	Claim Language	Infringement Evidence
		<p>by using ELU-2 and heating the microparticles to 85C for 3 minutes in an example of Step S160.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at 17:4-10 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the magnetic microparticles to 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at 17:37-43 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at col. 18:8-16 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160. DNA was eluted into 10 uL of ELU-2 and 2 ul of the eluate was used for real-time PCR in an example of Step S170.”) • U.S. Patent No. 9,382,532 at col. 18:41-47 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed twice with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at 19:22-27 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at 19:56-61 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500LL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at 20:17-32 (“Upon removal of the unbound supernatant in an example

Claim	Claim Language	Infringement Evidence
		<p>of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at col. 21:34-39 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500LL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at col. 22:2-8 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 or ELU-3 and heating the microparticles to 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at col. 28:667-67 (“Elution Solution ELU-3–40 mM KOH: ultrapure water (960 mL) and 1N KOH (40 mL).”) <p>US10010888 (Exhibit 55)</p> <ul style="list-style-type: none"> • Claim 17. The method of claim 14, further comprising delivering a release solution into the fluidic pathway, thereby producing a nucleic acid volume from the nucleic acid-magnetic bead sample. • U.S. Patent No. 10,010,888 at col. 11:7-10 (“The cartridge heater 153 functions to transfer heat to a heating region 224 of a microfluidic cartridge 210, for inducing a pH shift to release bound nucleic acids from magnetic beads within the heating region 224.”) • U.S. Patent No. 10,010,888 at col. 34:6-11 (“Step S442 functions to provide a heater, which, in combination with a release solution that provides a pH shift, facilitates a rapid and efficient unbinding of the nucleic acids from the magnetic beads.”)
1(v)	wherein the operating system is configured to actuate the first heat source to heat the lysate	The accused system comprises the operating system is configured to actuate the first heat source to heat the lysate solution in the first processing region to a second temperature greater than the first temperature.

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	<p>solution in the first processing region to a second temperature greater than the first temperature; and</p>	<p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMoDx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “A high pH NeuMoDx release reagent is dispensed into the s-channel to cover the beads and heat is applied to complete the denaturation process, resulting in released nucleic acid or eluent.” 2:55-58 • 2:58 Release reagent  <ul style="list-style-type: none"> • 3:04 Heat/denaturation

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		 <p>40500098_D-IFU-NeuMoDx-Extraction-Plate-US-ONLY (Exhibit 59)</p> <ul style="list-style-type: none"> • “The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate lysis buffer in the NeuMoDx Extraction Plate and is subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres.” <i>Id.</i> at 1. <p>40600100_-Rev-D-IFU-NeuMoDx-WASH-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 58)</p> <ul style="list-style-type: none"> • The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. <p>40600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 20)</p> <ul style="list-style-type: none"> • The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from

Claim	Claim Language	Infringement Evidence
		<p>unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres.</p> <p>40600103_Rev-D-IFU-NeuMoDx-Lysis-Buffer-4-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 66)</p> <ul style="list-style-type: none"> • The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of enriched Lim Broth is mixed with NeuMoDx Lysis Buffer 4 and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres dried in the NeuMoDx Extraction Plate. <p>On information and belief, accused system comprises the operating system is configured to actuate the first heat source to heat the lysate solution in the first processing region to a second temperature greater than the first temperature.</p> <p>US9540636 (Exhibit 54)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 14:22-28 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 500 uL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 30:60-61 (“ELUTION SOLUTION ELU-2 40 mM NaOH: ultrapure water (960 mL) and 1N NaOH (40 mL).”) • U.S. Patent No. 9,540,636 at col. 14:57-63 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 250 uL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 15:31-36 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL or 250 uL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step

Claim	Claim Language	Infringement Evidence
		<p>S160.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 15:67-16:6 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 16:57-64 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-1 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 30:58-59 (“ELUTION SOLUTION ELU-1 20 mM NaOH: ultrapure water (980 mL) and 1N NaOH (20 mL).”) • U.S. Patent No. 9,540,636 at col. 17:29-34 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 17:66-18:5 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the magnetic microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 18:37-43 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 19:13-19 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”)

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 19:51-57 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed twice with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 20:37-43 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 21:9-16 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160. DNA was eluted into 10 uL of ELU-2 and 2 uL of the eluate was used for real-time PCR in an example of Step S110.”) • U.S. Patent No. 9,540,636 at col. 21:42-48 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 22:5-11 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 22:67-23:6 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 23:42-48 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL


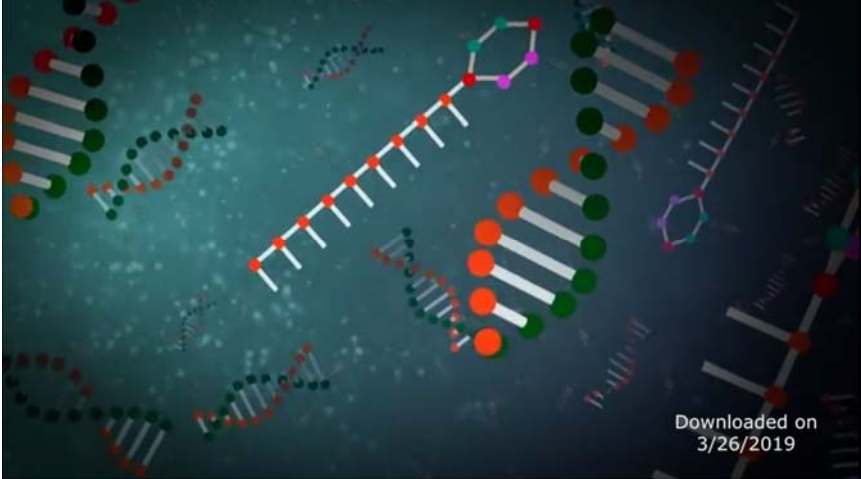
Claim	Claim Language	Infringement Evidence
		<p>of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 or ELU-3 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.")</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 30:62-63 ("ELUTION SOLUTION ELU-3 40 mM KOH: ultrapure water (960 mL) and 1N KOH (40 mL).") • U.S. Patent No. 9,540,636 at col. 24:23-29 ("Upon removal of the unbound Supernatant in an example of Step S140, the PAA affinity moieties coated onto magnetic microparticles were washed twice (2x) with 500 uL of WSH-1 solution in an example of Step S150, and then the captured RNA and DNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.") <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at col. 14:54-61 ("Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL or 250 uL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160. RNA was eluted into 10 uL of ELU-2 and 8 uL of the eluate was used for real-time RT-PCR in an example of Step 170.") • U.S. Patent No. 9,382,532 at col. 28:64-65 ("Elution Solution ELU-2 - 40 mM NaOH: ultrapure water (960 mL) and 1N NaOH (40 mL).") • U.S. Patent No. 9,382,532 at 15:19-26 ("Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160. RNA was eluted into 10 uL of ELU-2 and 2 LL of the eluate was used for real-time RT-PCR in an example of Step S170.") • U.S. Patent No. 9,382,532 at 16:2-14 ("DNA was allowed to bind to the DABAM affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature or 60 C depending on matrix used in examples of Step S130. Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-1 and heating the microparticles to 85 C for 3 minutes in an

Claim	Claim Language	Infringement Evidence
		<p>example of Step S160. DNA was eluted into 10 uL of ELU-1 and 8 ul of the eluate was used for real-time PCR in an example of Step S170.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at 28:62-63 (“Elution Solution ELU-1 - 20 mM NaOH: ultrapure water (980 mL) and 1N NaOH (20 mL).) • U.S. Patent No. 9,382,532 at 16:38-44 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500LL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at 17:4-10 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the magnetic microparticles to 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at 17:37-43 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at col. 18:8-16 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160. DNA was eluted into 10 uL of ELU-2 and 2 ul of the eluate was used for real-time PCR in an example of Step S170.”) • U.S. Patent No. 9,382,532 at col. 18:41-47 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed twice with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at 19:22-27 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1

Claim	Claim Language	Infringement Evidence
		<p>solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at 19:56-61 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500LL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at 20:17-23 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at col. 21:34-39 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500LL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at col. 22:2-8 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 or ELU-3 and heating the microparticles to 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at col. 28:667-67 (“Elution Solution ELU-3–40 mM KOH: ultrapure water (960 mL) and 1N KOH (40 mL).”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at col. 10:49-52 (“The cartridge heater 153 functions to transfer heat to a heating region 224 of a microfluidic cartridge 210, for inducing a pH shift to release bound nucleic acids from magnetic beads within the heating region 224.”) • U.S. Patent 9,050,594 at col. 29:63-30:7 (“Step S440 may additionally comprise delivering a wash solution through a portion of at least one fluidic pathway S444, such as the truncated fluidic pathway defined in Step S443, and delivering a release solution through a portion of at least one fluidic pathway S445, such as the truncated fluidic pathway defined in Step S443. Step

Claim	Claim Language	Infringement Evidence
		<p>S444 functions to wash at least one nucleic acid-magnetic bead sample in the set of nucleic acid-magnetic bead samples, and Step S445 functions to release at least one nucleic acid volume from the set of nucleic acid-magnetic bead samples. The heater provided in Step S442 may be activated after Step S445 to induce a pH shift.")</p> <p>US9339812 (Exhibit 26)</p> <ul style="list-style-type: none"> • Claim 8. The method of claim 7, wherein separating the volume of nucleic acids from the biological sample further comprises heating the first portion of the fluidic pathway to facilitate a pH shift, thus releasing nucleic acids from magnetic beads to produce the volume of nucleic acids. • Claim 20. The method of claim 19, wherein producing the set of nucleic acid volumes from the set of nucleic acid-magnetic bead samples comprises: upon passing a magnet through one of the set of slots of the cartridge platform of the molecular diagnostic module, providing a magnetic field spanning a portion of each fluidic pathway in the set of fluidic pathways, thus capturing the set of nucleic acid-magnetic bead samples; dispensing a wash solution into each fluidic pathway of the set of fluidic pathways; dispensing a release solution into each fluidic pathway of the set of fluidic pathways; and heating each fluidic pathway of the set of fluidic pathways to facilitate a pH shift, thus unbinding nucleic acids from magnetic beads to produce the set of nucleic acid volumes. • U.S. Patent No. 9,339,812 at col. 10:49-52 ("The cartridge heater functions to transfer heat to a heating region of a microfluidic cartridge, for inducing a pH shift to release bound nucleic acids from magnetic beads within the heating region.") • U.S. Patent No. 9,339,812 at col. 29:50-53 ("Step S442 functions to provide a heater, which, in combination with a release solution that provides a pH shift, facilitate a rapid and efficient unbinding of the nucleic acids from magnetic beads.") <p>US10010888 (Exhibit 55)</p> <ul style="list-style-type: none"> • Claim 17. The method of claim 14, further comprising delivering a release solution into the fluidic pathway, thereby producing a nucleic acid volume from the nucleic acid-magnetic bead sample. • U.S. Patent No. 10,010,888 at col. 11:7-10 ("The cartridge heater 153 functions to transfer heat to a heating region 224 of a microfluidic cartridge 210, for inducing a pH shift to release

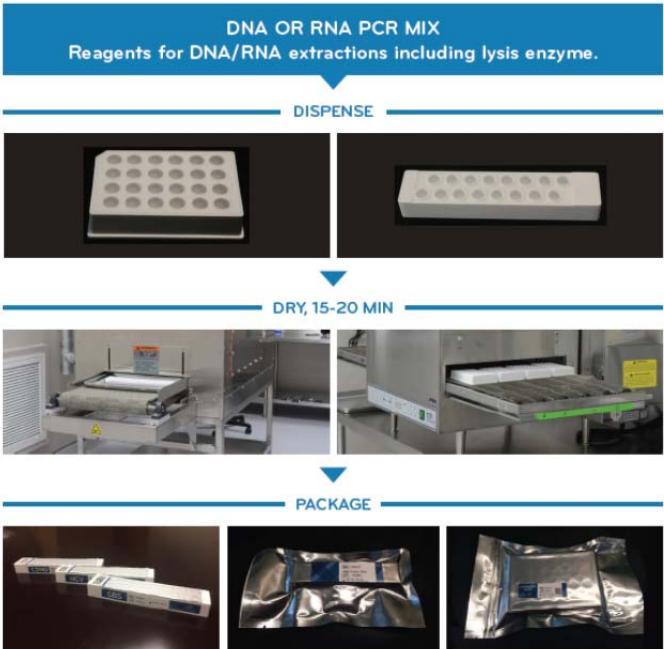
Claim	Claim Language	Infringement Evidence
		<p>bound nucleic acids from magnetic beads within the heating region 224.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 10,010,888 at col. 34:4-11 (“Step S442 functions to provide a heater, which, in combination with a release solution that provides a pH shift, facilitates a rapid and efficient unbinding of the nucleic acids from the magnetic beads.”)
1(w)	a second processing region comprising PCR reagents, the second processing region configured to receive the eluate solution containing polynucleotides and configured to place the eluate solution in contact with PCR reagents to form a PCR-ready solution.	<p>The accused system comprises a second processing region comprising PCR reagents, the second processing region configured to receive the eluate solution containing polynucleotides and configured to place the eluate solution in contact with PCR reagents to form a PCR-ready solution.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMoDx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936 (Exhibit 16)</p> <ul style="list-style-type: none"> “Liquid Handling Processing C: The Test Strip. After piercing the test strip, the liquid handling robot moves to the PCR port or p-port of the microfluidic cartridge, where it aspirates the eluate out of the cartridge into the pipette tip. Once the aspiration step is complete, the eluate is delivered to the appropriate wells in the NeuMoDx test strip, where it is dispensed and aspirated ten times to ensure homogeneous resuspension of the NeuDry PCR reagents. The sample mixes with primers and probes.” <i>Id.</i> at 3:12-3:36 3:36 test strip


Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none"> <li data-bbox="688 776 1045 808">• 3:46 Primers and probes  <p data-bbox="638 1328 1955 1386">40600145_-Rev-D-IFU-NeuMoD-LDT-Master-Mix-DNA-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 67)</p>

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> Upon lysis, the released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound DNA is eluted using NeuMoDx™ RELEASE Solution. The NeuMoDx System mixes the released DNA with the user provided LDT primers and probe(s) and then uses an aliquot of this solution to rehydrate the dried assay reagents in the NeuMoDx LDT MM Test Strip, DNA, which contains all the reagents necessary to perform a real-time PCR- specifically Taq DNA polymerase, dNTPS, MgCl2 and other optimized excipients and buffering agents. <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> The NeuMoDx Systems mix the released nucleic acid with assay specific primers and probe(s) as well as the dried Master Mix contained in a NeuMoDx test strip. The system then dispenses the prepared PCR-ready mixture into the NeuMoDx Cartridge where Real-Time PCR occurs. <p>40600106_Rev-D-IFU-NeuMoDx-Lysis-Buffer-1-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 63)</p> <ul style="list-style-type: none"> The NeuMoDx Systems mix the released nucleic acid with assay specific primers and probe(s) as well as the dried Master Mix contained in a NeuMoDx™ test strip. The system then dispenses the prepared PCR-ready mixture into the NeuMoDx Cartridge where Real-Time PCR occurs. <p>40600105_Rev-D-IFU-NeuMoDx-Lysis-Buffer-2-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 64)</p> <ul style="list-style-type: none"> The NeuMoDx Systems mix the released nucleic acid with assay specific primers and probe(s) as well as the dried Master Mix contained in a NeuMoDx™ test strip. The system then dispenses the prepared PCR-ready mixture into the NeuMoDx Cartridge where Real-Time PCR occurs. <p>40600104_Rev-D-IFU-NeuMoDx-Lysis-Buffer-3-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 65)</p> <ul style="list-style-type: none"> The NeuMoDx Systems mix the released nucleic acid with assay specific primers and probe(s) as well as the dried Master Mix contained in a NeuMoDx™ test strip. The system then dispenses the prepared PCR-ready mixture into the NeuMoDx Cartridge where Real-Time

Claim	Claim Language	Infringement Evidence
		<p>PCR occurs.</p> <p>40600103_Rev-D-IFU-NeuMoDx-Lysis-Buffer-4-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 66)</p> <ul style="list-style-type: none"> The NeuMoDx Systems mix the released nucleic acid with assay specific primers and probe(s) as well as the dried Master Mix contained in a NeuMoDx™ test strip. The system then dispenses the prepared PCR-ready mixture into the NeuMoDx Cartridge where Real-Time PCR occurs. <p>40600172_Rev-B-SDS-LDT-MM-RNA-Final-1.pdf (Exhibit 73)</p> <ul style="list-style-type: none"> The LDT Master Mix Test Strip, RNA (LDT MM, RNA) is a final finished product that contains reagents required to perform the Laboratory Developed Tests (LDT) on the NeuMoDx Molecular System for <i>in vitro</i> diagnosis only. Each test strip contains dried reagents in 16 individual wells and is sealed with a pierceable foil top. The final dried reagent is light pink. Exemptions for disclosing some component information are pursuant to CLP Article 1(5)(d) and 29 CFR 1910. 1200(g)(2)(i)(C)(1)&(2). <p>40600171_Rev-B-SDS-LDT-MM-DNA-FINAL.pdf (Exhibit 74)</p> <ul style="list-style-type: none"> The LDT Master Mix Test Strip, DNA (LDT MM, DNA) is a final finished product that contains reagents required to perform Laboratory Developed Tests (LDT) on the NeuMoDx Molecular System for <i>in vitro</i> diagnosis only. Each test strip contains dried reagents in 16 individual wells and is sealed with a pierceable foil top. The final dried reagent is light pink. Exemptions for disclosing some component information are pursuant to CLP Article 1(5)(d) and 29 CFR 1910. 1200(g)(2)(i)(C)(1)&(2). <p>40600170_Rev-C-SDS-NeuMoDx-CTNG-Test-Strip-200300-FINAL-08Mar2019 (Exhibit 75)</p> <ul style="list-style-type: none"> The CTNG Test Strip is a final finished product that contains reagents required to perform the NeuMoDx CTNG test on the NeuMoDx Molecular System for <i>in vitro</i> diagnosis only. Each test strip contains dried reagents in 16 individual wells and is sealed with a foil top. The final dried reagent is pink/purple. Exemptions for disclosing some component information are pursuant to CLP Article 1(5)(d) and 29 CFR 1910. 1200(g)(2)(i)(C)(1)&(2). <p>40600111_Rev-B-SDS-NeuMoDx-GBS-Test-Stip-DRAFT-14Mar2019.pdf (Exhibit 76)</p> <ul style="list-style-type: none"> The SDS for the GBS Test strip is for the final finished product for use in the laboratory. The

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		<p>Test Strip contains dried reagents stored in 16 individual wells per Test Strip and sealed with foil. The final dried reagent solution is pink/purple. Exemptions for disclosing some component information are pursuant to CLP Article 1(5)(d) and 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).</p> <p>NeuMoDx_Novel_Dry_Reagent_2017.pdf (Exhibit 80)</p> <ul style="list-style-type: none"> • The rapid development in nucleic acid based testing (NAT) in diagnosis has resulted in the routine use of qPCR in molecular diagnostic labs. Reagents for such qPCR assays have typically required the need for cold or frozen storage to maintain long term viability. Not only does the need for cold temperature storage offer substantial challenges to the implementation of NAT in resource limited settings, but the need for such cold storage equipment also severely complicates the development of next generation molecular diagnostic instrumentation with onboard reagents storage. Development of ambient stable NAT reagents will go a long way towards alleviating these significant drawbacks. Traditionally, lyophilization has been the method of choice for drying NAT reagents such as Taq polymerase. However, lyophilization requires expensive specialized equipment & reagents, is time intensive, and is practically impossible to implement in a continuous mode operation. NeuMoDx has developed a simple, cost effective, high-throughput, and rapid drying procedure capable of producing highly effective NAT reagents using a conventional conveyer oven. • Three types of molecular diagnostic reagents were dried using unique formulations of select excipients: 1) Extraction reagents including magnetic particles with a nucleic acid affinity matrix, lytic enzymes, and encapsulated DNA/RNA process controls. 2) DNA PCR reagents, and 3) RT-PCR reagents. DNA/RNA isolation was performed in a variety of clinical matrices using the ambient stable reagents. At the end of the isolation step, the eluted nucleic acids were used directly to reconstitute dried PCR or RT-PCR mix and qPCR was performed. The efficacy of these dried reagents was evaluated by both DNA and RNA assays, such as NeuMoDx HBV and HCV assays to assess critical analytical performance metrics such as limit of detection, linearity, quantification etc. Accelerated aging studies were also performed with all three dried reagent formulations to assess the long-term stability of these reagents.

Claim	Claim Language	Infringement Evidence
		<p style="text-align: center;">DRYING PROCESS</p>  <p>NeuMoDx-CVS-DryReagent_Poster-FNL.HD.pdf (Exhibit 81)</p> <ul style="list-style-type: none"> Reagents used for molecular diagnostics are typically stored frozen or at least refrigerated to maintain viability. The proprietary NeuDry process developed by NeuMoDx offers a simple, low cost, and rapid process using a conventional conveyor oven to produce ready to use, ambient condition stable reagents capable of providing long open-shelf life for active reagents used in molecular diagnostic testing. The performance of reagents produced using the NeuDry process across wide variety of molecular diagnostic applications is presented here. Three types of reagents formulated and optimized for both long term storage and in-use shelf life were produced using the NeuDry process - 1) Nucleic acid isolation reagents including NeuMag™ affinity particles, lytic enzyme, and encapsulated DNA/RNA process controls, 2) PCR Master mix, and 3) RT-PCR Master mix. Performance of the NeuDry reagents was initially evaluated against the liquid version of these reagents. Efficacy of the

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		<p>reagents was further evaluated by testing across a variety of clinical matrices encompassing both DNA and RNA targets. Long-term stability and in-use shelf life was determined via accelerated and real time stability studies on fully automated NeuMoDx Molecular System.</p> <p style="text-align: center;">DRYING PROCESS</p> <div style="text-align: center;">  <p>The diagram illustrates the drying process in four stages: 1. Formulation (PCR or RT-PCR and Nucleic Acid Extraction), 2. Dispense (into a multi-well plate), 3. Drying (15-20 minutes in a laboratory setting), and 4. Packaging (into individual test strips and then into bags).</p> </div> <p>40600293-SDS-201500-vA-EBV-quant.pdf (Exhibit 77)</p> <ul style="list-style-type: none"> The NeuMoDx EBV Quant Test Strip is a final finished product that contains reagents required

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		<p>to perform the human Epstein-Barr virus (EBV) test on the NeuMoDx Molecular System. Each test strip contains dried reagents in 16 individual wells and is sealed with a pierceable foil top. The final dried reagent solution is light pink. Exemptions for disclosing some component information are pursuant to CLP Article 1(5)(d) and 29 CFR 1910. 1200(g)(2)(i)(C)(1)&(2).</p> <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 10. The system of claim 1, further comprising an assay strip comprising at least one reagent well, each containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module. • Claim 24. The system of claim 23, further comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample, a lysing reagent, and a sample process control, wherein the capture plate facilitates production of at least one biological sample combined with magnetic beads; an assay strip comprising at least one reagent well containing molecular diagnostic reagent volume configured to be combined with a nucleic acid volume of the set of nucleic acid volumes to produce at least one nucleic acid-reagent mixture; and a liquid handling system configured to transfer at least one biological sample combined with magnetic beads from the capture plate to the molecular diagnostic module,

Claim	Claim Language	Infringement Evidence
		<p>transfer at least one nucleic acid-reagent mixture from the assay strip back to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) • U.S. Patent No. 9,050,594 at col. 3:33-41 (“The liquid handling system 250 then aspirates the set of nucleic acids from the microfluidic cartridge 210 contained within the molecular diagnostic module 130, combines the set of nucleic acids with a set of molecular diagnostic reagents using an assay strip 190, and dispenses the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the microfluidic cartridge 210 within the molecular diagnostic module 130.”) • U.S. Patent No. 9,050,594 at col. 19:45-51 (“As shown in FIGS. 18A and 18B, the assay strip 190 comprises an assay strip substrate 191 comprising a set of wells 192, and typically a puncturable foil seal 195, and functions to facilitate combination of a set of nucleic acid samples with a set of molecular diagnostic reagents for amplification and/or detection of a nucleic acid sequence or sequences.”) • U.S. Patent No. 9,050,594 at col. 21:7-15 (“In one variation, the assay strip 190 may be prepackaged with a set of molecular diagnostic reagents, such that each well 193 in the set of wells 192 is prepackaged with a quantity of molecular diagnostic reagents. The set of wells 192 may then be sealed by the puncturable foil seal 195, which is configured to be punctured by an external element that delivers volumes of nucleic acid samples to be combined with the set of molecular diagnostic reagents.”) • U.S. Patent No. 9,050,594 at 30:28-44 (“Step S450 recites combining each nucleic acid volume of the set of nucleic acid volumes with a molecular diagnostic reagent of a set of molecular

Claim	Claim Language	Infringement Evidence
		<p>diagnostic reagents to produce a set of nucleic acid-reagent mixtures, which functions to prepare the set of nucleic acid volumes to be detected. For each nucleic acid volume in the set of nucleic acid volumes, Step S450 preferably comprises aspirating an entire volume of the nucleic acid volume from its corresponding fluidic pathway, and transferring the nucleic acid volume to a well containing a molecular diagnostic reagent. Preferably, all nucleic acid volumes in the set of nucleic acid volumes are aspirated and combined with molecular diagnostic reagents simultaneously using a multichannel fluid delivery system; however, each nucleic acid volume in the set of nucleic acid volumes may alternatively be aspirated and combined with molecular diagnostic reagents independently of the other nucleic acid volumes.”)</p> <p>US9441219 (Exhibit 53)</p> <ul style="list-style-type: none"> • Claim 7: The molecular diagnostic module of claim 1, further comprising: a capture plate comprising a well containing a set of magnetic beads, a lysing reagent, and a sample process control, configured to be combined with the biological sample, wherein the capture plate facilitates production of a magnetic bead-sample from the biological sample and the set of magnetic beads; an assay strip comprising a reagent well containing a molecular diagnostic reagent volume configured to be combined with the nucleic acid volume processed from the magnetic-bead sample, thereby generating a nucleic acid-reagent mixture; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the cartridge, transfer the nucleic acid volume from the cartridge to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip back to the cartridge. • U.S. Patent No. 9,441,219 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”)

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> US 9,441,219 at col. 3:41-49 (“The liquid handling system 250 then aspirates the set of nucleic acids from the micro-fluidic cartridge 210 contained within the molecular diagnostic module 130, combines the set of nucleic acids with a set of molecular diagnostic reagents using an assay strip 190, and dispenses the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the microfluidic cartridge 210 within the molecular diagnostic module 130.”) U.S. Patent No. 9,441,219 at col. 20:9-15 (“A shown in FIGS. 18A and 18B, the assay strip 190 comprises an assay strip substrate 191 comprising a set of wells 192, and typically a puncturable foil seal 195, and functions to facilitate combination of a set of nucleic acid samples with a set of molecular diagnostic reagents for amplification and/or detection of a nucleic acid sequence or sequences.”) U.S. Patent No. 9,441,219 at col. 31:9-14 (“Step S450 recites combining each nucleic acid volume of the set of nucleic acid volumes with a molecular diagnostic reagent of a set of molecular diagnostic reagents to produce a set of nucleic acid-reagent mixtures, which functions to prepare the set of nucleic acid volumes to be detected.”) <p>US9339812 (Exhibit 26)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,339,812 at col. 3:33-46 (“The liquid handling system 250 then aspirates the set of nucleic acids from the microfluidic cartridge 210 contained within the molecular diagnostic module 130, combines the set of nucleic acids with a set of molecular diagnostic reagents using an assay strip 190, and dispenses the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the microfluidic cartridge 210 within the molecular diagnostic module 130. The detection chamber heaters 157, optical subsystem 180 and valve actuation sub-system 170 of the molecular diagnostic module 130 then facilitate analysis of the set of nucleic acid-reagent mixtures by a processor configured to display information on a user interface.”)

EXHIBIT 89


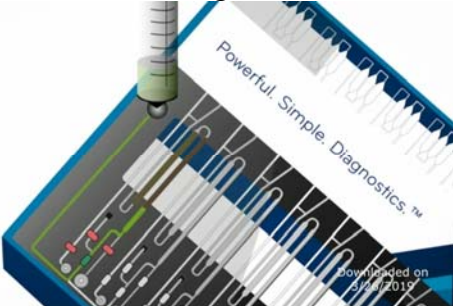
EXHIBIT 89

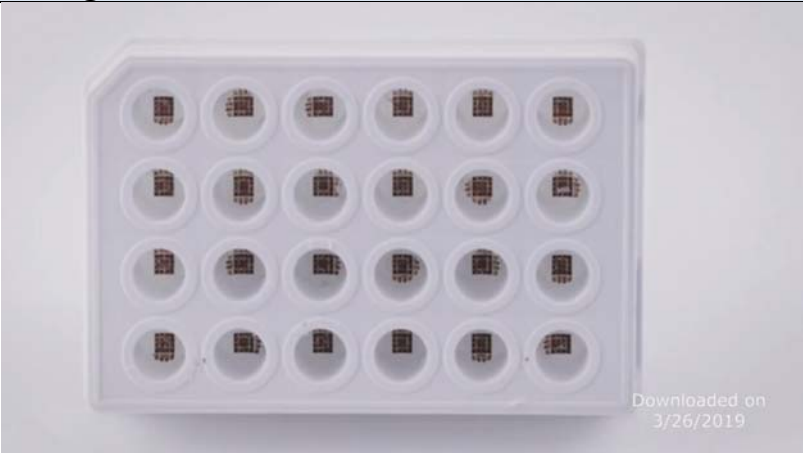
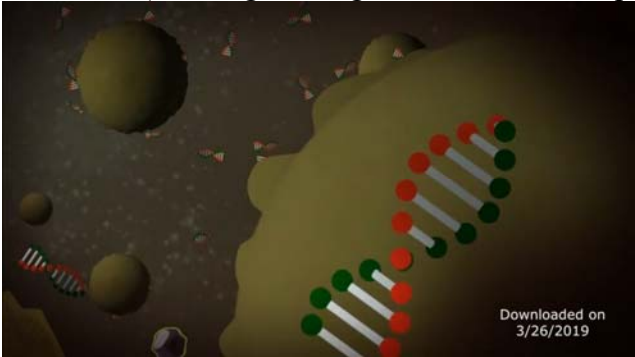
U.S. Patent No. 10,494,663 Infringement Chart

Claim	Claim Language	Infringement Evidence
1(a)	A method of isolating polynucleotides from a biological sample in a molecular diagnostic system, the method comprising	<p>To the extent the preamble is limiting, the accused workflow comprises isolating polynucleotides from a biological sample in a molecular diagnostic system.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-products/, last visited June 5, 2019 (Exhibit 12)</p> <div data-bbox="625 553 1509 1248"> </div> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> • “The NeuMoDx™ 96 Molecular System is designed for the automated extraction and isolation of

Claim	Claim Language	Infringement Evidence
		<p>nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.”</p> <ul style="list-style-type: none"> • “The NeuMoDx™ 288 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 288 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” <p><i>NeuMoDx_Quant_HCV_CVS_2018.pdf (Exhibit 18)</i></p> <ul style="list-style-type: none"> • Describing “...microfluidic cartridges capable of performing independent sample processing and real-time PCR.” <div data-bbox="695 672 1455 1143" data-label="Image"> </div> <p><i>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</i></p> <ul style="list-style-type: none"> • “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System... The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid

Claim	Claim Language	Infringement Evidence
		<p>extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.”</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “The NeuMoDx Molecular N96 and N288 are fully automated sample to result molecular diagnostics platforms. They provide continuous random access processing with initial results in one hour and operator walk away time of up to eight hours. NeuMoDx Molecular solutions utilize four distinct processes to produce the final patient results.” <i>Id.</i> at 0:00-0:28 • “Each extraction plate well is then heated independently for 10 minutes to ensure proper lysing and binding of the nucleic acids to the paramagnetic beads. The temperatures applied range from 37 degrees Celsius to 60 degrees Celsius, resulting in the flexibility to process a wide variety of DNA and RNA IVD and LDT tests simultaneously.” <i>Id.</i> at 1:05-1:16 • “A precise volume of air is then applied to remove any remaining liquid into the waste chamber. NeuMoDx wash solution is pumped via the fluid port into the microfluidic cartridge to remove all unbound material, followed by another volume of air to remove excess wash solution.” <i>Id.</i> at 2:39-2:43 • 2:43 Wash solution <div data-bbox="699 927 1207 1219"> </div> • 2:45 Wash solution in s-channel

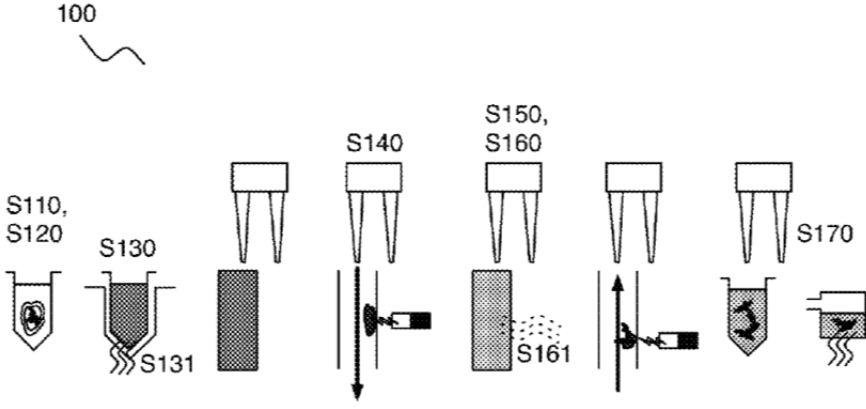
Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none"> • 2:57 “High pH NeuMoDx release reagent is dispensed into the s-channel to cover the beads, and heat is applied to the denaturation process, resulting in released nucleic acid or eluate.” • 2:58 Release reagent 
1(b)	receiving the biological sample in a lysing container in the system	<p>The accused workflow comprises receiving the biological sample in a lysing container in the system.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p>

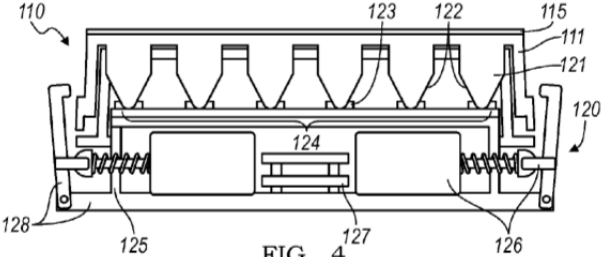
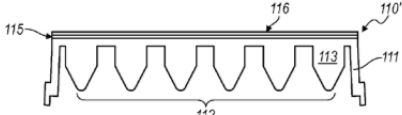
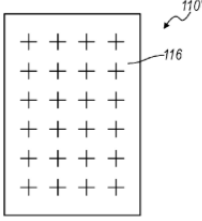
Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none"> • “Liquid Handling Processing A: Lysis and Capture. Dispensing lysis buffer. Dispensing lysis buffer and patient specimen into extraction plate. The liquid handling robot delivers lysis buffer and patient specimen to the extraction plate, which has 24 independent wells which contain NeuDry affinity-coated paramagnetic beads. Each mixture is aspirated and dispensed five times to ensure homogeneity of the solution. During the transfer of patient specimen to the extraction plate the liquid handling robot uses pre-defined no-fly zones to reduce the potential of contamination.” <i>Id.</i> at 0:28-0:40. • <i>Id.</i> at 1:16 (showing binding of nucleic acids to paramagnetic beads). 

Claim	Claim Language	Infringement Evidence										
		<p>“Patents”, http://www.neumodx.com/patents/, (Exhibit 47) demonstrating that NeuMoDx marks its products with US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; 9,452,430; 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; 10,010,888; 9,382,532; 9,540,636; 9,499,896; 10,239,060; 9,539,576; 10,226,771, 9,637,775; and 10,093,963</p> <h2>PATENTS</h2> <table><tr><th>Product</th><th>Patents</th></tr><tr><td>CARTRIDGE</td><td>US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.</td></tr><tr><td>P02 (overall system and method)</td><td>US Patent Nos. 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; and 10,010,888. CN Patent No. 201380009286.3.</td></tr><tr><td>EXTRACTION PLATE</td><td>US Patent Nos. 9,382,532; and 9,540,636. DE Patent No. 60 2013 056 932.0. DK Patent No. 2912174. EP Patent No. EP-B-2912174. ES Patent No. 300330453. FR Patent No. 2912174. GB Patent No. 2912174. IT Patent No. 502019000064944. NO Patent No. 2912174. SE Patent No. 2912174.</td></tr><tr><td>XPCR MODULE</td><td>US Patent Nos. 9,499,896; 10,239,060; 9,539,576; 10,226,771; 9,637,775; 10,093,963; 9,604,213; and 10,010,888.</td></tr></table> <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none">Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of	Product	Patents	CARTRIDGE	US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.	P02 (overall system and method)	US Patent Nos. 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; and 10,010,888. CN Patent No. 201380009286.3.	EXTRACTION PLATE	US Patent Nos. 9,382,532; and 9,540,636. DE Patent No. 60 2013 056 932.0. DK Patent No. 2912174. EP Patent No. EP-B-2912174. ES Patent No. 300330453. FR Patent No. 2912174. GB Patent No. 2912174. IT Patent No. 502019000064944. NO Patent No. 2912174. SE Patent No. 2912174.	XPCR MODULE	US Patent Nos. 9,499,896; 10,239,060; 9,539,576; 10,226,771; 9,637,775; 10,093,963; 9,604,213; and 10,010,888.
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		<p>a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 3. The method of claim 1, wherein receiving the binding moiety solution, comprising the set of affinity moiety-coated microparticles, comprises receiving a set of magnetic microparticles covalently bonded to a set of affinity moiety molecules, and wherein contacting the binding moiety solution with the biological sample comprises aspirating the binding moiety solution along with the biological sample from the process chamber and dispensing the binding moiety solution with the biological sample to the process chamber. • Claim 4. The method of claim 3, wherein incubating the moiety-sample mixture comprises heating the moiety-sample solution to a temperature in the range of 25-95° C. for 5-60 minutes, thus simultaneously lysing the biological sample and facilitating binding of nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles. • U.S. Patent No. 9,382,532 at 3:4-34 (“As shown in FIGS. 1A and 2, a method 100 for nucleic acid isolation comprises receiving a binding moiety solution within a process chamber S110; mixing the binding moiety solution with a biological sample, within the process chamber, in order to produce a moiety-sample solution S120; incubating the moiety-sample solution during a time window S130, thereby producing a lysed solution comprising a moiety-bound nucleic acid volume and a waste volume; separating the moiety-bound nucleic acid volume from the waste volume S140; washing the moiety-bound nucleic acid volume S150; and releasing a nucleic acid sample from the moiety-bound nucleic acid volume S160. • U.S. Patent No. 9,382,532 at 4:56-5:2 (“Step S120 recites mixing the binding moiety solution with a biological sample, within the process chamber, in order to produce a moiety-sample solution, which functions to initiate lysis of the biological sample and enable target nucleic acids to bind to affinity moieties of the binding moiety solution. Preferably, binding of target nucleic acids to affinity moieties is facilitated by the appropriate pH of the binding solution, as shown in FIG. 1C; however, binding can be facilitated by any other suitable mechanism. In a variation involving an appropriate pH in the binding solution, mixing and binding can occur at a low pH, which produces a positively charged

Claim	Claim Language	Infringement Evidence
		<p>affinity moiety that is attracted to negatively charged nucleic acid molecules. Specific examples of affinity moieties that function via a pH shift are described in Section 2 below.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at 5:3-7(“In Step S120, the process chamber can be any suitable vessel, as shown in FIG. 1A, or a suitable capture plate, such as that described in U.S. patent application Ser. No. 13/766,359, entitled “System and Method for Processing and Detecting Nucleic Acids”, as shown in FIG. 1B.”) • U.S. Patent No. 9,382,532 at 5:42-6:2 (“Step S130 recites incubating the moiety-sample solution during a time window, and functions to produce a lysed moiety-sample solution comprising a moiety-bound nucleic acid volume (e.g., a volume of nucleic acids reversibly bonded to the set of affinity moiety-coated microparticles) and a waste volume. In Step S130, the moiety-sample solution can be incubated using any suitable heating apparatus, as shown in FIG. 1A, or a suitable capture plate heater, such as that described in U.S. patent application Ser. No. 13/766,359, entitled "System and Method for Processing and Detecting Nucleic Acids", as shown in FIG. 1B. In Step S130, the nucleic acid is released from within the cell or other structure that it is contained within, and binds to the microparticles coupled with the affinity moiety, while other unbound components form a waste volume for later removal, as shown in FIG. 1 C. Preferably, the process chamber containing the moiety-sample solution (e.g., lysis, clean-up, binding reagents and the biological sample) is incubated for a defined period of time at a temperature preferably in the range of 25-95 C, wherein time and temperature parameters are biological sample-dependent. Example parameters for different biological samples are described briefly below, and further in Section 3 below. Alternatively, the moiety-sample solution can be transferred to another vessel for incubation in variations of Step S130. Furthermore, in variations of Steps S110, S120, and S130, any or all of the lysis, proteolytic and binding steps can occur simultaneously in the process chamber or any other suitable vessel, and are not required to be discrete steps.”) • U.S. Patent No. 9,382,532 at FIG. 1B.

Claim	Claim Language	Infringement Evidence
		 <p data-bbox="1066 690 1218 722">FIGURE 1B</p> <p data-bbox="604 776 919 808">US9050594 (Exhibit 24)</p> <ul data-bbox="651 816 2026 1396" style="list-style-type: none"> • Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a

Claim	Claim Language	Infringement Evidence
		<p>heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”)</p> <ul style="list-style-type: none"> U.S. Patent no. 9,050,594 at col. 1:63-65 (“FIG. 4 depicts an embodiment of a capture plate module to facilitate lysis of a biological sample and combination of the biological sample with magnetic beads;”)  <p style="text-align: center;">FIG. 4</p> <ul style="list-style-type: none"> U.S. Patent no. 9,050,594 at col.1:66-67 (“FIGS. 5A-5B depict an alternative embodiment of a capture plate;”)  <p style="text-align: center;">FIG. 5A</p>  <p style="text-align: center;">FIG. 5B</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at col. 3:14-20 (“In one example workflow of the system 100, a liquid

Claim	Claim Language	Infringement Evidence
		<p>handling system 250 aspirates a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), and dispenses the set of biological samples into a capture plate 110 to be lysed and combined with magnetic beads (contain-ing a proprietary affinity coating to bind the nucleic acids to the magnetic beads) by a capture plate module 120.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 col. 4:15-19 (“The set of wells 112 of the capture plate substrate 111 function to receive at least one biological sample with contain or are suspected of potentially containing nucleic acids, and to facilitate combination of the biological sample with a set of magnetic beads 119.”) • U.S. Patent No. 9,050,594 col. 6:6-13 (“Preferably, the capture plate module 120 functions to facilitate lysis of a biological sample deposited into a well 113 of the capture plate, and to facilitate binding of nucleic acids (i.e., within a lysed biological sample) to a quantity of magnetic beads 119 within a well 113 of the capture plate 110. In a specific example, the capture plate module 120 has dimensions of 108 mm x 156 mm x 45 mm and is configured to rest on a flat surface.”) • U.S. Patent No. 9,050,594 at col. 27:27-36 (“Step S410 recites combining each biological sample of the set of biological samples with a quantity of magnetic beads to produce a set of magnetic bead-sample mixtures, and functions to prepare a set of biological samples to be lysed and combined with magnetic beads. For each biological sample, Step S410 preferably comprises aspirating a portion of the volume of the biological sample from a sample container (possibly containing an aqueous solution prior to addition of biological sample), and transferring the portion of the biological sample to a well containing a set of magnetic beads.”) <p>US9441219 (Exhibit 53)</p> <ul style="list-style-type: none"> • Claim 7. The molecular diagnostic module of claim 1, further comprising: a capture plate comprising a well containing a set of magnetic beads, a lysing reagent, and a sample process control, configured to be combined with the biological sample, wherein the capture plate facilitates production of a magnetic bead-sample from the biological sample and the set of magnetic beads; an assay strip comprising a reagent well containing a molecular diagnostic reagent volume configured to be combined with the nucleic acid volume processed from the magnetic-bead sample, thereby generating a nucleic acid-reagent mixture; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the cartridge, transfer the nucleic acid volume from the cartridge to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip back to the cartridge. • Claim 14. The system of claim 8, further comprising a capture plate comprising a well containing a set

Claim	Claim Language	Infringement Evidence
		<p>of magnetic beads, a lysing reagent, and a sample process control, configured to be combined with the biological sample, wherein the capture plate facilitates production of a magnetic bead-sample from the biological sample and the set of magnetic beads; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the cartridge, and configured to transfer a nucleic acid volume processed from the magnetic bead-sample from the cartridge.</p> <ul style="list-style-type: none"> U.S. Patent No. 9,441,219 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.
1(c)	contacting the biological sample with a buffer solution and a lysing reagent in the lysing container,	<p>The accused workflow comprises contacting the biological sample with a buffer solution and a lysing reagent in the lysing container.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “Liquid Handling Processing A: Lysis and Capture. Dispensing lysis buffer. Dispensing lysis buffer and patient specimen into extraction plate. The liquid handling robot delivers lysis buffer and patient specimen to the extraction plate, which has 24 independent wells which contain NeuDry affinity-coated paramagnetic beads. Each mixture is aspirated and dispensed five times to ensure homogeneity of the solution. During the transfer of patient specimen to the extraction plate the liquid handling robot uses pre-defined no-fly zones to reduce the potential of contamination.” <i>Id.</i> at 0:28-0:40. <p>40600177_Rev-C-SDS-NeuMoDx-Lysis-Buffer-3-Final.pdf (Exhibit 70)</p>

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		<table><tr><th colspan="4">Composition (Hazardous Components Only)</th></tr><tr><th>Name</th><th>Identifiers</th><th>%</th><th>GHS-US classification</th></tr><tr><td>Guanidine hydrochloride</td><td>CAS Number: 50-01-1</td><td>< 50%</td><td>Skin Irritation. 2; Eye Irritation. 2A</td></tr><tr><td>Sodium azide</td><td>CAS Number: 26628-22-8</td><td>< 0.1%</td><td>Not a hazardous substance or mixture at this concentration.</td></tr></table> <p>40600176_Rev-C-SDS_-NeuMoDx-Lysis-Buffer-2-Final.pdf (Exhibit 69)</p> <table><tr><th colspan="4">Composition (Hazardous Components Only)</th></tr><tr><th>Name</th><th>Identifiers</th><th>%</th><th>GHS-US classification</th></tr><tr><td>Guanidine hydrochloride</td><td>CAS Number: 50-01-1</td><td>< 50%</td><td>Skin Irritation. 2; Eye Irritation. 2A</td></tr><tr><td>Sodium azide</td><td>CAS Number: 26628-22-8</td><td>< 0.1%</td><td>Not a hazardous substance or mixture at this concentration.</td></tr></table> <p>40600175_Rev-C-SDS-NeuMoDx-Lysis-Buffer-1-Final.pdf (Exhibit 68)</p> <p>Mixtures Chemical Characterization: Mixture of a chemical and/or biological substances for <i>in vitro</i> diagnostic use.</p> <table><tr><th colspan="4">Composition (Hazardous Components Only)</th></tr><tr><th>Name</th><th>Identifiers</th><th>%</th><th>GHS-US classification</th></tr><tr><td>Guanidine hydrochloride</td><td>CAS Number: 50-01-1</td><td>< 50%</td><td>Skin Irritation. 2; Eye Irritation. 2A</td></tr><tr><td>Maleic acid</td><td>CAS Number: 110-16-7</td><td><1%</td><td>Not a hazardous substance or mixture at this concentration.</td></tr><tr><td>Sodium azide</td><td>CAS Number: 26628-22-8</td><td>< 0.1%</td><td>Not a hazardous substance or mixture at this concentration.</td></tr></table> <p>40600110_Rev-C-SDS-NeuMoDx-Extraction-Plate-FINAL-13Mar2019-1.pdf (Exhibit 93)</p>	Composition (Hazardous Components Only)				Name	Identifiers	%	GHS-US classification	Guanidine hydrochloride	CAS Number: 50-01-1	< 50%	Skin Irritation. 2; Eye Irritation. 2A	Sodium azide	CAS Number: 26628-22-8	< 0.1%	Not a hazardous substance or mixture at this concentration.	Composition (Hazardous Components Only)				Name	Identifiers	%	GHS-US classification	Guanidine hydrochloride	CAS Number: 50-01-1	< 50%	Skin Irritation. 2; Eye Irritation. 2A	Sodium azide	CAS Number: 26628-22-8	< 0.1%	Not a hazardous substance or mixture at this concentration.	Composition (Hazardous Components Only)				Name	Identifiers	%	GHS-US classification	Guanidine hydrochloride	CAS Number: 50-01-1	< 50%	Skin Irritation. 2; Eye Irritation. 2A	Maleic acid	CAS Number: 110-16-7	<1%	Not a hazardous substance or mixture at this concentration.	Sodium azide	CAS Number: 26628-22-8	< 0.1%	Not a hazardous substance or mixture at this concentration.
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Sodium azide	CAS Number: 26628-22-8	< 0.1%	Not a hazardous substance or mixture at this concentration.																																																			

Claim	Claim Language	Infringement Evidence								
		<div>8.1 Occupational Exposure Limits</div> <table><tr><th>Chemical/Biological name</th><th>Limit</th><th>Control Parameters</th><th>Basis</th></tr><tr><td>Proteinase K</td><td>Not available</td><td>Not available</td><td>USA. Occupational Exposure Limits (OSHA). Table Z-1 limits for air contaminants.None</td></tr></table> <div>NeuMoDx_Novel_Dry_Reagent_2017.pdf (Exhibit 80)</div> <ul style="list-style-type: none">NMDx extraction plate is designed to be used on the NeuMoDx Molecular System to lyse bacteria and virus pathogens and capture DNA/RNA. It contains proteinase K, magnetic particles and DNA/RNA sample process control (SPC). The reagents were dried in a 24 well plate using the NMDx standard procedure, vacuum sealed foil pouch and stored at 40°C for accelerated study. The efficiency of the dried reagents was evaluated with two assays, Group B strep in Lim Broth and HCV in BaseMatrix. After equivalent to 1 yr at 22°C, no loss in activities was observed based on Ct and EPR values. <div>40600106_Rev-D-IFU-NeuMoDx-Lysis-Buffer-1-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 63)</div> <ul style="list-style-type: none">NeuMoDx™ Lysis Buffer 1 is a proprietary buffer used for the efficacious extraction of nucleic acids from unprocessed clinical specimens on the NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems (NeuMoDx™ System(s)) when used in conjunction with other NeuMoDx™ reagents such as NeuMoDx™ Extraction Plate, NeuMoDx™ WASH Solution, and the NeuMoDx™ RELEASE Solution, which are used for all tests processed on the NeuMoDx Systems. NeuMoDx Lysis Buffer 1 can be used for extraction of viral or bacterial DNA from human plasma and serum samples. <div>40600105_Rev-D-IFU-NeuMoDx-Lysis-Buffer-2-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 64)</div> <ul style="list-style-type: none">NeuMoDx™ Lysis Buffer 2 is a proprietary buffer used for the efficacious extraction of nucleic acids from unprocessed clinical specimens on the NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems (NeuMoDx™ System(s)) when used in conjunction with other NeuMoDx™ reagents such as NeuMoDx™ Extraction Plate, NeuMoDx™ WASH Solution, and the NeuMoDx™ RELEASE Solution, which are used for all tests processed on the NeuMoDx Systems. NeuMoDx Lysis Buffer 2 can be used for extraction of bacterial DNA from human urine samples.	Chemical/Biological name	Limit	Control Parameters	Basis	Proteinase K	Not available	Not available	USA. Occupational Exposure Limits (OSHA). Table Z-1 limits for air contaminants.None
Chemical/Biological name	Limit	Control Parameters	Basis							
Proteinase K	Not available	Not available	USA. Occupational Exposure Limits (OSHA). Table Z-1 limits for air contaminants.None							

Claim	Claim Language	Infringement Evidence
		<p>40600104_Rev-D-IFU-NeuMoDx-Lysis-Buffer-3-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 65)</p> <ul style="list-style-type: none"> The NeuMoDx™ Lysis Buffer 3 is a proprietary buffer used for the efficacious extraction of nucleic acids from unprocessed clinical specimens on the NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems (NeuMoDx™ System(s)) when used in conjunction with other NeuMoDx™ reagents such as NeuMoDx™ Extraction Plate, NeuMoDx™ WASH Solution, and the NeuMoDx™ RELEASE Solution, which are used for all tests processed on the NeuMoDx Systems. NeuMoDx Lysis Buffer 3 can be used for extraction of viral RNA from human plasma and serum samples. <p>40600103_Rev-D-IFU-NeuMoDx-Lysis-Buffer-4-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 66)</p> <ul style="list-style-type: none"> The NeuMoDx™ Lysis Buffer 4 is a proprietary lysis and binding buffer that when used in conjunction with NeuMoDx™ supplied consumables, NeuMoDx™ Extraction Plate, NeuMoDx™ WASH Solution, and NeuMoDx™ RELEASE Solution, enables the extraction of DNA from Gram-positive bacteria from clinical samples on the NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems (NeuMoDx™ System(s)). <p>40600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 20)</p> <ul style="list-style-type: none"> The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. <p>40600100_Rev-D-IFU-NeuMoDx-WASH-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 58)</p> <ul style="list-style-type: none"> The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. <p>40500098_D-IFU-NeuMoDx-Extraction-Plate-US-ONLY (Exhibit 59)</p> <ul style="list-style-type: none"> “The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell

Claim	Claim Language	Infringement Evidence
		<p>lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate lysis buffer in the NeuMoDx Extraction Plate and is subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres.” <i>Id.</i> at 1.</p> <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx™ lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. <p>US9540636 (Exhibit 54)</p> <ul style="list-style-type: none"> Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the first fluidic pathway of the cartridge; and washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway. Claim 14. A method for nucleic acid extraction, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles; mixing the binding moiety solution with a

Claim	Claim Language	Infringement Evidence
		<p>biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and target RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; and magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the microfluidic pathway of the cartridge.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 5:1-9 (“Step S120 recites mixing the binding moiety solution with a biological sample, within the process chamber, in order to produce a moiety-sample solution, which functions to initiate lysis of the biological sample and enable target nucleic acids to bind to affinity moieties of the binding moiety solution. Preferably, binding of target nucleic acids to affinity moieties is facilitated by the appropriate pH of the binding solution, as shown in FIG. 1C; however, binding can be facilitated by any other suitable mechanism.”) • U.S. Patent No. 9,540,636 at col. 3:45-53 (“The method 100 can be performed in any container or process chamber that is configured to contain a suitable concentration of affinity moiety-coated microparticles, facilitate suitable buffer conditions to allow for binding (e.g., buffer conditions providing a suitably low pH), contain suitable amounts of proteolytic or other enzymes for effective lysis or removal of inhibitory substances, and provide suitable thermal conditions that collectively enable binding of nucleic acids to the affinity moiety-coated microparticles.”) • U.S. Patent No. 9,540,636 at col. 4:12-22 (“Preferably, the binding moiety solution comprises a suitable concentration of an affinity moiety configured to selectively bind to target nucleic acids, such as an affinity moiety described in Section 2 below; however, the binding moiety solution can additionally or alternatively comprise additional components, such as a collection buffer (e.g., low pH buffer, high salt content buffer), proteolytic enzymes (e.g., Proteinase K, other proteases), additional lysis reagents, and/or any other suitable process reagents that facilitate binding of nucleic acids to the affinity moieties.”) • U.S. Patent No. 9,540,636 at col. 4:46-55 (“In a specific example of this variation of Step S110, the microparticles are magnetic beads (e.g., magnetic, paramagnetic, superparamagnetic) with any suitable hydrophilicity (e.g., hydrophobic, hydrophilic), wherein the magnetic beads are coated with the affinity moiety and simultaneously received within the process chamber along with a low-pH buffer solution, proteolytic enzymes, and lytic reagents. In this specific example, magnetic separation can

Claim	Claim Language	Infringement Evidence
		<p>be used to facilitate further processing and isolation of nucleic acids bound to the affinity moieties coupled to magnetic beads.”)</p> <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> • Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10. • Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first

Claim	Claim Language	Infringement Evidence
		<p>position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the microfluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20 uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at col. 3:35-43 (“The method 100 can be performed in any container or process chamber that is configured to contain a suitable concentration of affinity moiety-coated microparticles, facilitate suitable buffer conditions to allow for binding (e.g., buffer conditions providing a suitably low pH), contain suitable amounts of proteolytic or other enzymes for effective lysis or removal of inhibitory substances, and provide suitable thermal conditions that collectively enable binding of nucleic acids to the affinity moiety-coated microparticles.”) • U.S. Patent No. 9,382,532 at 4:1-11 (“Preferably, the binding moiety solution comprises a suitable concentration of an affinity moiety configured to selectively bind to target nucleic acids, such as an affinity moiety described in Section 2 below; however, the binding moiety solution can additionally or alternatively comprise additional components, such as a collection buffer (e.g., low pH buffer, high salt content buffer), proteolytic enzymes (e.g., Proteinase K, other proteases), additional lysis reagents, and/or any other suitable process reagents that facilitate binding of nucleic acids to the affinity moieties.”) <p>US9604213 (Exhibit 30)</p> <ul style="list-style-type: none"> • Claim 9. The system of claim 8, wherein the liquid handling system is further configured to automatically combine the biological sample with a buffer solution, couple to a filter, and deliver the biological sample with the buffer solution through the filter and into the capture plate. • U.S. Patent No. 9,604,213 at 32:7-13 (“Additionally or alternatively, the method 400 can include combining each biological sample of the set of biological samples with buffer solution S405 prior to combining each biological sample of the set of biological samples with a quantity of magnetic beads, which functions to further decrease sample preparation burden on an entity processing and/or analyzing the set of biological samples.”) <p>US9050594 (Exhibit 24)</p>

Claim	Claim Language	Infringement Evidence												
		<ul style="list-style-type: none">Claim 4. The system of claim 1, wherein the capture plate comprises a set of wells and a foil seal configured to seal each well of the set of wells, wherein each well in the set of wells contain a set of magnetic beads, a set of lysing reagents, and a sample process control.U.S. Patent No. 9,050,594 at col. 4:50-55 (“Each quantity of magnetic beads 119 may be accompanied by lysing reagents (e.g. proteinase K) and a sample process control comprising nucleic acid sequences for DNA and RNA, which function to lyse biological samples and to provide a mechanism by which sample process controls may be later detected to verify processing fidelity and assay accuracy.”)												
1(d)	wherein the buffer solution has a pH of about 8.5 or less;	<p>The accused workflow comprises contacting the biological sample with a buffer solution and a lysing reagent in the lysing container, wherein the buffer solution has a pH of about 8.5 or less.</p> <p>40600175_REV-C-SDS-NeuMoDx-Lysis-Buffer-1-Final.pdf (Exhibit 68)</p> <p>9.1 General Information</p> <table><tr><td>Form:</td><td>Liquid</td></tr><tr><td>Color:</td><td>Clear, with a slightly yellow tinge</td></tr><tr><td>Odor:</td><td>odorless</td></tr><tr><td>Odor Threshold:</td><td>Not determined</td></tr><tr><td>pH Value at 20°C (68°F):</td><td>4.45 – 4.9</td></tr><tr><td>Melting point/melting range:</td><td>Not determined</td></tr></table> <p>40600176 Rev-C-SDS -NeuMoDx-Lysis-Buffer-2-Final.pdf (Exhibit 69)</p>	Form:	Liquid	Color:	Clear, with a slightly yellow tinge	Odor:	odorless	Odor Threshold:	Not determined	pH Value at 20°C (68°F):	4.45 – 4.9	Melting point/melting range:	Not determined
Form:	Liquid													
Color:	Clear, with a slightly yellow tinge													
Odor:	odorless													
Odor Threshold:	Not determined													
pH Value at 20°C (68°F):	4.45 – 4.9													
Melting point/melting range:	Not determined													

Claim	Claim Language	Infringement Evidence
		<p>9.1 General Information</p> <p>Form: Liquid</p> <p>Color: Clear, with a slightly yellow tinge</p> <p>Odor: odorless</p> <p>Odor Threshold: Not determined</p> <p>pH Value at 20°C (68°F): 4.2 – 5.2</p> <p>Melting point/melting range: Not determined</p> <p>40600177_Rev-C-SDS-NeuMoDx-Lysis-Buffer-3-Final.pdf (Exhibit 70)</p> <p>9.1 General Information</p> <p>Form: Liquid</p> <p>Color: Clear, with a slightly yellow tinge</p> <p>Odor: Odorless</p> <p>Odor Threshold: Not determined</p> <p>pH Value at 20°C (68°F): 4.9 – 5.1</p> <p>Melting point/melting range: Not determined</p> <p>40600112_Rev-B-SDS-NeuMoDx-Lysis-Buffer-4-FINAL.pdf (Exhibit 71)</p> <p>9.1 General Information</p> <p>Form: Liquid</p> <p>Color: Clear, with a slightly yellow tinge</p> <p>Odor: odorless</p> <p>Odor Threshold: Not determined</p> <p>pH Value at 20°C (68°F): 4.45 – 4.9</p> <p>Melting point/melting range: Not determined</p>

Claim	Claim Language	Infringement Evidence
1(e)	heating the biological sample in the lysing container to a first temperature between about 30° C and about 50° C,	<p>The accused workflow comprises heating the biological sample in the lysing container to a first temperature between about 30° C and about 50° C.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMoDx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “Each extraction plate well is then autonomously heated for as little as six minutes to ensure proper lysing and binding of the nucleic acids to the paramagnetic beads. The temperatures applied range from 37° C to over 90° C, resulting in the flexibility to process a wide variety of DNA and RNA IVD and LDT tests simultaneously.” 1:07-1:32 <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> • “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System... The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.” <p>On information and belief, the accused system comprises heating the biological sample in the lysing container to a first temperature between about 30° C and about 50° C.</p> <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> • Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at

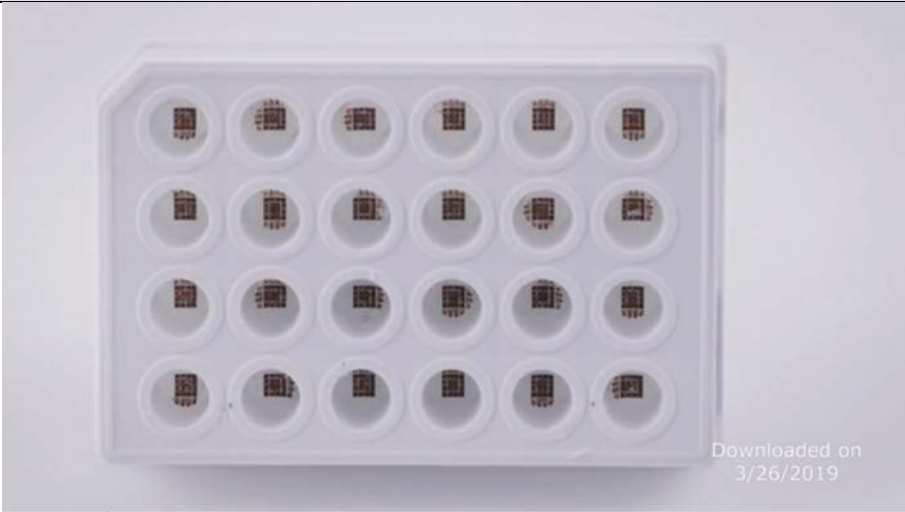
Claim	Claim Language	Infringement Evidence
		<p>a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 3. The method of claim 1, wherein receiving the binding moiety solution, comprising the set of affinity moiety-coated microparticles, comprises receiving a set of magnetic microparticles covalently bonded to a set of affinity moiety molecules, and wherein contacting the binding moiety solution with the biological sample comprises aspirating the binding moiety solution along with the biological sample from the process chamber and dispensing the binding moiety solution with the biological sample to the process chamber. • Claim 4: The method of claim 3, wherein incubating the moiety-sample mixture comprises heating the moiety-sample solution to a temperature in the range of 25-95°C for 5-60 minutes, thus simultaneously lysing the biological sample and facilitating binding of nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles. • U.S. Patent No. 9,382,532 at 5:3-7 (“In Step S120, the process chamber can be any suitable vessel, as shown in FIG. 1A, or a suitable capture plate, such as that described in U.S. patent application Ser. No. 13/766,359, entitled “System and Method for Processing and Detecting Nucleic Acids”, as shown in FIG. 1B.”) • U.S. Patent No. 9,382,532 at 17:27-37 (“An eighth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, simulated Swab specimens as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target. In the eighth example, a buccal Swab (obtained from a donor) was added to 1 mL of DNA Collection Buffer 1 (CBD 1) containing 0.4 mg. Proteinase K and then spiked with 10 pg of GBS DNA in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37C in an example of Step S130.”) • U.S. Patent No. 9,382,532 at col. 28:49-51 (“CBD-1 (SP1: ultrapure water (93.1 mL), 1 M Tris pH 7.0 (50 mL), sodium citrate (50.88 g), boric acid (1.24 g), 0.5M EDTA pH 8.0 (2 mL), and Triton-X 100

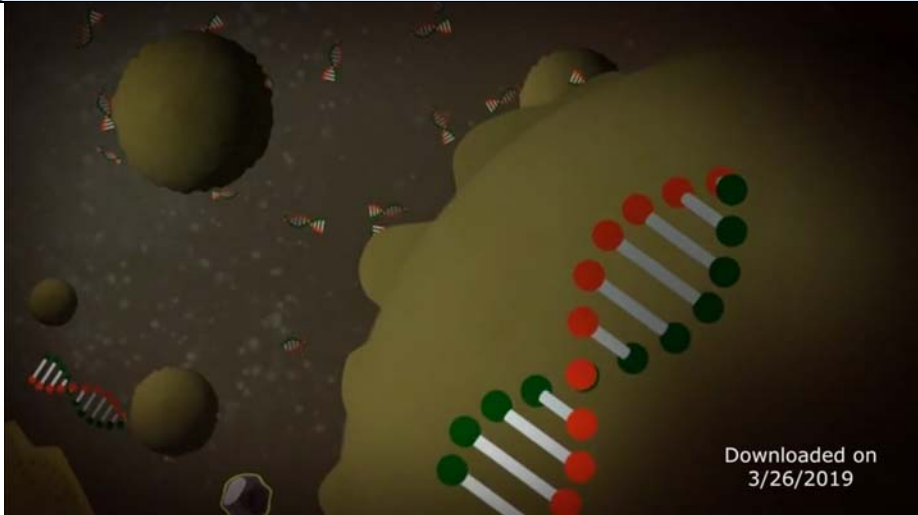
Claim	Claim Language	Infringement Evidence
		<p>(10 mL).”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,382,532 at col. 17:60-18:8 (“A ninth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, simulated Swab transport media specimens as representative biological samples and Group B Streptococcus (GBS) DNA as the model target. In the ninth example 500 uL of M4 Transport Media (M4) or Universal Transport Media (UTM) containing a buccal Swab (obtained from a donor) was spiked with 10pg of GBS DNA and then mixed with 500 uL of DNA Collection Buffer 3 (CBD-3) and 0.4 mg of Proteinase K in examples of Steps S110 and S120. For comparison, “Dry Swab’ samples were prepared by adding a buccal swab to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg Proteinase K and then spiked with 10 pg of GBS DNA. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37C in an example of Step S130.”) U.S. Patent No. 9,382,532 at col. 28:55-57 (“CBD-3 ISP3: ultrapure water (862 mL), 1 M Tris pH 7.0 (100 mL), sodium citrate (11.76 g), boric acid (2.48 g), 0.5M EDTA pH 8.0 (4 mL), and Triton-X 100 (20 mL).”) U.S. Patent 9,382,532 at col. 18:34-41 (“In the tenth example, 100 uL whole blood (donor, obtained from Bioreclamation, Inc.) was added to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg. Proteinase K and then spiked with 10pg of GBS DNA in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37 C in an example of Step S130.”) U.S. Patent No. 9,382,532 at col. 21:27-33 (“In the fifteenth example, 500 uL of Urine (obtained from a donor) was spiked with mpg of GBS DNA and then mixed with 500 uL of DNA Collection Buffer 2 (CBD-2) in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature, 37 C, 1(C, or 60 C in examples of Step S130.”) U.S. Patent No. 9,382,532 at col. 28:52-54 (“CBD-2 SP2: ultrapure water (480 mL), 1 M Tris pH 7.0 (100 mL), sodium citrate (11.76 g), boric acid (2.48 g), 0.5M EDTA pH 8.0 (400 mL), and Triton-X 100 (20 mL).”) U.S. Patent No. 9,382,532 at col. 22:37-43 (“In the seventeenth example, 500 uL of M4 was spiked with ten-fold serial dilutions of 1 uL of EV viral particle lysate and 1 uL of GBSDNA and then mixed with 500 uL of RNA Collection Buffer 3 (CBR-3) in examples of Steps S110 and S120. RNA and DNA were allowed to bind to the PAA affinity moieties for 10 minutes at 37 C in an example of Step S130.”)

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> U.S. Patent No. 9,382,532 at col. 28:46-48 (“CBR-3 2x EDTA only Buffer: ultrapure water (560 mL), 1M Tris pH 8.0 (20 mL), 0.5M EDTA pH 8.0 (400 mL), and Triton-X 100 (20 mL).”) <p>US9540636 (Exhibit 54)</p> <ul style="list-style-type: none"> Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the first fluidic pathway of the cartridge; and washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway. Claim 6: The method of claim 3, wherein incubating the moiety-sample mixture comprises heating the moiety-sample solution to a temperature above 25° C for at least 5 minutes, thus simultaneously lysing the biological sample and facilitating the binding of nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles. Claim 14. A method for nucleic acid extraction, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles; mixing the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and target RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; and magnetically separating the set of moiety-bound nucleic acid particles from the moiety-

Claim	Claim Language	Infringement Evidence
		<p>sample mixture, within the microfluidic pathway of the cartridge.</p> <ul style="list-style-type: none"> U.S. Patent No. 9,540,646 at col. 6:2-9 (“Preferably, the process chamber containing the moiety-sample solution (e.g., lysis, clean-up, binding reagents and the biological sample) is incubated for a defined period of time at a temperature preferably in the range of 25-95 C, wherein time and temperature parameters are biological sample-dependent. Example parameters for different biological samples are described briefly below, and further in Section 3 below.”) U.S. Patent No. 9,540,646 at col. 6:24-31 (“In a variation of the first example, enteroviral particles treated with Proteinase K can be incubated and lysed within a modified temperature range of 37-60C for optimal activity of the proteinase enzyme. In a second example of Step S130, a nasal Swab containing Staphylococcus aureus bacteria is incubated at approximately 95 C to ensure thorough lysis of the gram-positive bacteria.”) U.S. Patent No. 9,540,636 at col. 18:31-37 (“In the eighth example, a buccal Swab (obtained from a donor) was added to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg. Proteinase K and then spiked with 10 pg of GBS DNA in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37 C in an example of Step S130.”) U.S. Patent No. 9,540,636 at col. 30:45-47 (“CBD-1 (SP1: ultrapure water (93.1 mL), 1 M Tris pH 7.0 (50 mL), sodium citrate (5.88 g), boric acid (1.24 g), 0.5M EDTA pH 8.0 (2 mL), and Triton-X 100 (10 mL).”) U.S. Patent No. 9,540,636 at col. 19:2-13 (“In the ninth example 500 uL of M4 Transport Media (M4) or Universal Transport Media (UTM) containing a buccal Swab (obtained from a donor) was spiked with 10 pg of GBS DNA and then mixed with 500 uL of DNA Collection Buffer 3 (CBD-3) and 0.4 mg of Proteinase K in examples of Steps S110 and S120. For comparison, “Dry Swab” samples were prepared by adding a buccal swab to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg. Proteinase K and then spiked with 10 pg of GBS DNA. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37 C in an example of Step S130.”) U.S. Patent No. 9,540,636 at col. 30:51-53 (“CBD-3 ISP3: ultrapure water (862 mL), 1 M Tris pH 7.0 (100 mL), sodium citrate (11.76 g), boric acid (2.48 g), 0.5M EDTA pH 8.0 (4 mL), and Triton-X 100 (20 mL).”) U.S. Patent No. 9,540,636 at col. 19:44-50 (“In the tenth example, 100 uL whole blood (donor, obtained from Bioreclamation, Inc.) was added to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg. Proteinase K and then spiked with 10 pg of GBS DNA in examples of Steps S110

Claim	Claim Language	Infringement Evidence
		<p>and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37 C in an example of Step S130.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 30:48-50 (“CBD-2 SP2: ultrapure water (480 mL), 1 M Tris pH 7.0 (100 mL), sodium citrate (11.76 g), boric acid (2.48 g), 0.5M EDTA pH 8.0 (400 mL), and Triton-X 100 (20 mL).”) • U.S. Patent No. 9,540,636 at col. 24:16-22 (“In the seventeenth example, 500 uL of M4 was spiked with ten-fold serial dilutions of 1 uL of EV viral particle lysate and 1 LL of GBS DNA and then mixed with 500 uL of RNA Collection Buffer 3 (CBR-3) in examples of Steps S110 and S120. RNA and DNA were allowed to bind to the PAA affinity moieties for 10 minutes at 37C in an example of Step S130.”)
1(f)	wherein the polynucleotides are extracted from the biological sample into a lysate solution;	<p>The accused workflow comprises heating the biological sample in the lysing container to a first temperature between about 30° C and about 50° C, wherein the polynucleotides are extracted from the biological sample into a lysate solution.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • <i>Id.</i> at 0:40 (showing the extraction plate).

Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none"> • “Each extraction plate well is then autonomously heated for as little as six minutes to ensure proper lysing and binding of the nucleic acids to the paramagnetic beads. The temperatures applied range from 37° C to over 90° C, resulting in the flexibility to process a wide variety of DNA and RNA IVD and LDT tests simultaneously.” 1:07-1:32 • <i>Id.</i> at 1:16 (showing binding of nucleic acids to paramagnetic beads).

Claim	Claim Language	Infringement Evidence
		 <p>40600106_Rev-D-IFU-NeuMoDx-Lysis-Buffer-1-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 63)</p> <ul style="list-style-type: none"> • NeuMoDx™ Lysis Buffer 1 is a proprietary buffer used for the efficacious extraction of nucleic acids from unprocessed clinical specimens on the NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems (NeuMoDx™ System(s)) when used in conjunction with other NeuMoDx™ reagents such as NeuMoDx™ Extraction Plate, NeuMoDx™ WASH Solution, and the NeuMoDx™ RELEASE Solution, which are used for all tests processed on the NeuMoDx Systems. NeuMoDx Lysis Buffer 1 can be used for extraction of viral or bacterial DNA from human plasma and serum samples. • The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/removal of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with NeuMoDx Lysis Buffer 1 and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. NeuMoDx Lysis Buffer 1 is especially formulated and optimized for extraction of bacterial or viral DNA in plasma and serum samples, by providing an optimal environment for cell/particle lysis and DNA binding to occur. The stringent formulation of the buffer also inhibits or reduces any nuclease activity

Claim	Claim Language	Infringement Evidence
		<p>present in the sample thereby protecting the viral or bacterial DNA from degradation.</p> <p>40600105_Rev-D-IFU-NeuMoDx-Lysis-Buffer-2-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 64)</p> <ul style="list-style-type: none"> NeuMoDx™ Lysis Buffer 2 is a proprietary buffer used for the efficacious extraction of nucleic acids from unprocessed clinical specimens on the NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems (NeuMoDx™ System(s)) when used in conjunction with other NeuMoDx™ reagents such as NeuMoDx™ Extraction Plate, NeuMoDx™ WASH Solution, and the NeuMoDx™ RELEASE Solution, which are used for all tests processed on the NeuMoDx Systems. NeuMoDx Lysis Buffer 2 can be used for extraction of bacterial DNA from human urine samples. The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/removal of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed urine specimen is mixed with NeuMoDx Lysis Buffer 2 and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. NeuMoDx Lysis Buffer 2 is especially formulated and optimized for extraction of bacterial DNA from human urine samples, by providing an optimal environment for cell/particle lysis and DNA binding to occur. The stringent formulation of the buffer also inhibits or reduces any nuclease activity present in the sample thereby protecting the bacterial DNA from degradation. <p>40600104_Rev-D-IFU-NeuMoDx-Lysis-Buffer-3-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 65)</p> <ul style="list-style-type: none"> The NeuMoDx™ Lysis Buffer 3 is a proprietary buffer used for the efficacious extraction of nucleic acids from unprocessed clinical specimens on the NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems (NeuMoDx™ System(s)) when used in conjunction with other NeuMoDx™ reagents such as NeuMoDx™ Extraction Plate, NeuMoDx™ WASH Solution, and the NeuMoDx™ RELEASE Solution, which are used for all tests processed on the NeuMoDx Systems. NeuMoDx Lysis Buffer 3 can be used for extraction of viral RNA from human plasma and serum samples. The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/removal of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of unprocessed specimen is mixed with NeuMoDx Lysis Buffer 3 and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. NeuMoDx Lysis Buffer 3 is especially formulated and optimized for extraction of viral RNA from human plasma and serum

Claim	Claim Language	Infringement Evidence
		<p>samples by providing an optimal environment for cell/particle lysis and nucleic acid binding to occur. The stringent formulation of the buffer also inhibits or reduces any nuclease activity present in the sample thereby protecting the viral RNA from degradation.</p> <ul style="list-style-type: none"> • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600103_Rev-D-IFU-NeuMoDx-Lysis-Buffer-4-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 66)</p> <ul style="list-style-type: none"> • The NeuMoDx™ Lysis Buffer 4 is a proprietary lysis and binding buffer that when used in conjunction with NeuMoDx™ supplied consumables, NeuMoDx™ Extraction Plate, NeuMoDx™ WASH Solution, and NeuMoDx™ RELEASE Solution, enables the extraction of DNA from Gram-positive bacteria from clinical samples on the NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems (NeuMoDx™ System(s)). • The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of enriched Lim Broth is mixed with NeuMoDx Lysis Buffer 4 and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres dried in the NeuMoDx Extraction Plate. • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 20)</p> <ul style="list-style-type: none"> • The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres

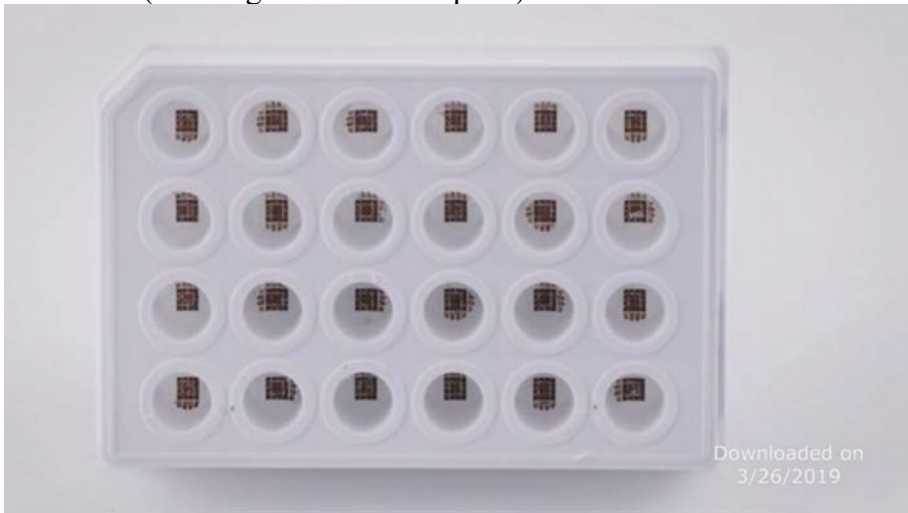
Claim	Claim Language	Infringement Evidence
		<p>(along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution.</p> <p>40600100_Rev-D-IFU-NeuMoDx-WASH-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 58)</p> <ul style="list-style-type: none"> • The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40500098_D-IFU-NeuMoDx-Extraction-Plate-US-ONLY (Exhibit 59)</p> <ul style="list-style-type: none"> • “The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate lysis buffer in the NeuMoDx Extraction Plate and is subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres.” <i>Id.</i> at 1. • “The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution.” <i>Id.</i> at 1. <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> • The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx™ lysis buffer and

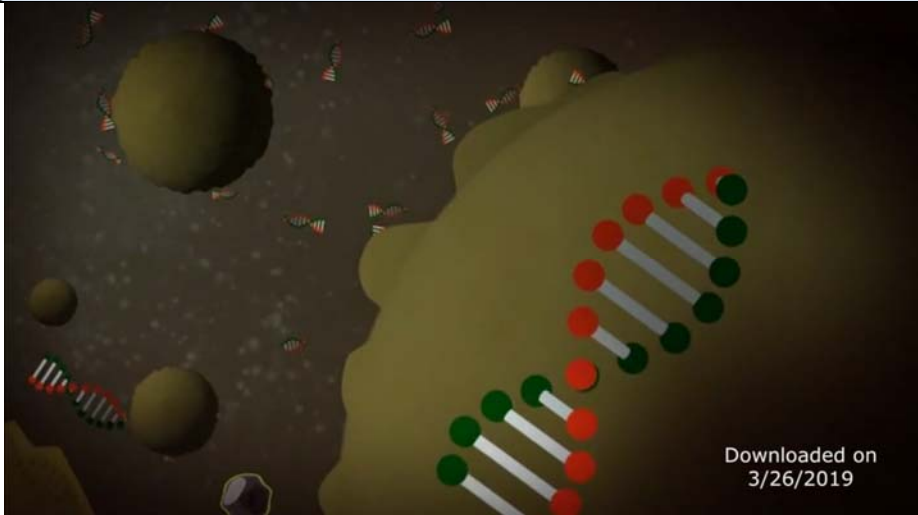
Claim	Claim Language	Infringement Evidence								
		<p>subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres.</p> <ul style="list-style-type: none">The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound nucleic acid is eluted using the NeuMoDx™ RELEASE Solution. <p>40600110_Rev-C-SDS-NeuMoDx-Extraction-Plate-FINAL-13Mar2019-1.pdf (Exhibit 93)</p> <p>8.1 Occupational Exposure Limits</p> <table><tr><th>Chemical/Biological name</th><th>Limit</th><th>Control Parameters</th><th>Basis</th></tr><tr><td>Proteinase K</td><td>Not available</td><td>Not available</td><td>USA. Occupational Exposure Limits (OSHA). Table Z-1 limits for air contaminants.None</td></tr></table> <p>NeuMoDx_Novel_Dry_Reagent_2017.pdf (Exhibit 80)</p> <ul style="list-style-type: none">NMDx extraction plate is designed to be used on the NeuMoDx Molecular System to lyse bacteria and virus pathogens and capture DNA/RNA. It contains proteinase K, magnetic particles and DNA/RNA sample process control (SPC). The reagents were dried in a 24 well plate using the NMDx standard procedure, vacuum sealed foil pouch and stored at 40°C for accelerated study. The efficiency of the dried reagents was evaluated with two assays, Group B strep in Lim Broth and HCV in BaseMatrix. After equivalent to 1 yr at 22°C, no loss in activities was observed based on Ct and EPR values. <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none">Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to	Chemical/Biological name	Limit	Control Parameters	Basis	Proteinase K	Not available	Not available	USA. Occupational Exposure Limits (OSHA). Table Z-1 limits for air contaminants.None
Chemical/Biological name	Limit	Control Parameters	Basis							
Proteinase K	Not available	Not available	USA. Occupational Exposure Limits (OSHA). Table Z-1 limits for air contaminants.None							

Claim	Claim Language	Infringement Evidence
		<p>reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the microfluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20 uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction. • U.S. Patent No. 9,382,532 at 3:4-34 (“As shown in FIGS. 1A and 2, a method 100 for nucleic acid isolation comprises receiving a binding moiety solution within a process chamber S110; mixing the binding moiety solution with a biological sample, within the process chamber, in order to

Claim	Claim Language	Infringement Evidence
		<p>produce a moiety-sample solution S120; incubating the moiety-sample solution during a time window S130, thereby producing a lysed solution comprising a moiety-bound nucleic acid volume and a waste volume; separating the moiety-bound nucleic acid volume from the waste volume S140; washing the moiety-bound nucleic acid volume S150; and releasing a nucleic acid sample from the moiety-bound nucleic acid volume S160.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at 4:56-5:2 (“Step S120 recites mixing the binding moiety solution with a biological sample, within the process chamber, in order to produce a moiety-sample solution, which functions to initiate lysis of the biological sample and enable target nucleic acids to bind to affinity moieties of the binding moiety solution. Preferably, binding of target nucleic acids to affinity moieties is facilitated by the appropriate pH of the binding solution, as shown in FIG. 1C; however, binding can be facilitated by any other suitable mechanism. In a variation involving an appropriate pH in the binding solution, mixing and binding can occur at a low pH, which produces a positively charged affinity moiety that is attracted to negatively charged nucleic acid molecules. Specific examples of affinity moieties that function via a pH shift are described in Section 2 below.”) • U.S. Patent No. 9,382,532 at 5:42-6:2 (“ Step S130 recites incubating the moiety-sample solution during a time window, and functions to produce a lysed moiety-sample solution comprising a moiety-bound nucleic acid volume (e.g., a volume of nucleic acids reversibly bonded to the set of affinity moiety-coated microparticles) and a waste volume. In Step S130, the moiety-sample solution can be incubated using any suitable heating apparatus, as shown in FIG. 1A, or a suitable capture plate heater, such as that described in U.S. patent application Ser. No. 13/766,359, entitled "System and Method for Processing and Detecting Nucleic Acids", as shown in FIG. 1B. In Step S130, the nucleic acid is released from within the cell or other structure that it is contained within, and binds to the microparticles coupled with the affinity moiety, while other unbound components form a waste volume for later removal, as shown in FIG. 1 C. Preferably, the process chamber containing the moiety-sample solution (e.g., lysis, clean-up, binding reagents and the biological sample) is incubated for a defined period of time at a temperature preferably in the range of 25-95 C, wherein time and temperature parameters are biological sample-dependent. Example parameters for different biological samples are described briefly below, and further in Section 3 below. Alternatively, the moiety-sample solution can be transferred to another vessel for incubation in variations of Step S130. Furthermore, in variations of Steps S110, S120, and S130, any or all of the lysis, proteolytic and binding steps can occur simultaneously in the process chamber or any other suitable vessel, and are not required to be discrete steps.”)

Claim	Claim Language	Infringement Evidence
		<p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 4. The system of claim 1, wherein the capture plate comprises a set of wells and a foil seal configured to seal each well of the set of wells, wherein each well in the set of wells contain a set of magnetic beads, a set of lysing reagents, and a sample process control. • Claim 24. The system of claim 23, further comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample, a lysing reagent, and a sample process control, wherein the capture plate facilitates production of at least one biological sample combined with magnetic beads; an assay strip comprising at least one reagent well containing molecular diagnostic reagent volume configured to be combined with a nucleic acid volume of the set of nucleic acid volumes to produce at least one nucleic acid-reagent mixture; and a liquid handling system configured to transfer at least one biological sample combined with magnetic beads from the capture plate to the molecular diagnostic module, transfer at least one nucleic acid-reagent mixture from the assay strip back to the molecular diagnostic module • U.S. Patent No. 9,050,594 at col. 4:50-55 (“Each quantity of magnetic beads 119 may be accompanied by lysing reagents (e.g. proteinase K) and a sample process control comprising nucleic acid sequences for DNA and RNA, which function to lyse biological samples and to pro-vide a mechanism by which sample process controls may be later detected to verify processing fidelity and assay accuracy.”) • U.S. Patent No. 9,050,594 at col. 27:23-26 (“The method 400 functions to isolate and extract a set of nucleic acid volumes from a biological sample, and to facilitate analysis of the nucleic acid volumes according to at least one molecular diagnostic protocol.”) • U.S. Patent No. 9,050,594 at col. 28:34-38 (“Step S420 recites heating the set of magnetic bead-sample mixtures to produce a set of nucleic acid-magnetic bead samples, and functions to incubate the set of magnetic bead-sample mixtures in order to lyse biological matter, and release nucleic acids to be bound to magnetic beads.”)
1(g)	contacting the polynucleotides with a plurality of magnetic binding particles in the lysing container,	<p>The accused workflow comprises contacting the polynucleotides with a plurality of magnetic binding particles in the lysing container.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire

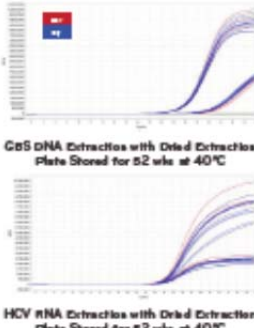
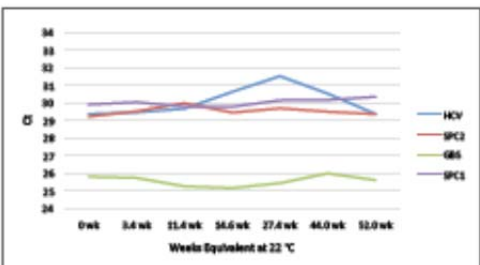
Claim	Claim Language	Infringement Evidence
		<p>molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge.”</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • <i>Id.</i> at 0:40 (showing the extraction plate).  <ul style="list-style-type: none"> • “Each extraction plate well is then autonomously heated for as little as six minutes to ensure proper lysing and binding of the nucleic acids to the paramagnetic beads. The temperatures applied range from 37° C to over 90° C, resulting in the flexibility to process a wide variety of DNA and RNA IVD and LDT tests simultaneously.” 1:07-1:32 • <i>Id.</i> at 1:16 (showing binding of nucleic acids to paramagnetic beads).

Claim	Claim Language	Infringement Evidence
		 <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound nucleic acid is eluted using the NeuMoDx™ RELEASE Solution. <p>40500098_D-IFU-NeuMoDx-Extraction-Plate-US-ONLY (Exhibit 59)</p> <ul style="list-style-type: none"> • “The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate lysis buffer in the NeuMoDx Extraction Plate and is subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres.” <i>Id.</i> at 1. • “The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution.” <i>Id.</i> at 1.

Claim	Claim Language	Infringement Evidence
		<p>40600100_Rev-D-IFU-NeuMoDx-WASH-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 58)</p> <ul style="list-style-type: none"> The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 20)</p> <ul style="list-style-type: none"> The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600103_Rev-D-IFU-NeuMoDx-Lysis-Buffer-4-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 66)</p> <ul style="list-style-type: none"> The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of enriched Lim Broth is mixed with NeuMoDx Lysis Buffer 4 and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres dried in the NeuMoDx Extraction Plate.

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600104_Rev-D-IFU-NeuMoDx-Lysis-Buffer-3-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 65)</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600105_Rev-D-IFU-NeuMoDx-Lysis-Buffer-2-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 64)</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600106_Rev-D-IFU-NeuMoDx-Lysis-Buffer-1-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 63)</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600094_D-IFU-NeuMoDx-Cartidge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> “NeuMoDx™ Cartridge: Instructions for Use...The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound nucleic acid is eluted using the NeuMoDx™ RELEASE Solution.” <p>40600129_D-IFU-GBS-Test-Strip-US-only.pdf (Exhibit 60)</p> <ul style="list-style-type: none"> “NeuMoDx™ GBS Test Strip: Instructions for Use...The released nucleic acids are captured by

Claim	Claim Language	Infringement Evidence
		<p>magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are loaded in to the NeuMoDx™ Cartridge where the unbound, non-DNA components are further washed away with NeuMoDx™ WASH Solution and the bound DNA is eluted using NeuMoDx™ RELEASE Solution.”</p> <p>40600145_-Rev-D-IFU-NeuMoD-LDT-Master-Mix-DNA-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 67)</p> <ul style="list-style-type: none"> “NeuMoDx™ LDT Master Mix, DNA: Instructions for Use...Upon lysis, the released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bund nucleic acids, are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound DNA is eluted using NeuMoDx™ RELEASE Solution.” <p>40600146_D-IFU-NeuMoDx-LDT-Master-Mix-RNA-US-ONLY (Exhibit 62)</p> <ul style="list-style-type: none"> “NeuMoDx™ LDT Master Mix, RNA: Instructions for Use...Upon lysis, the released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound RNA is eluted using NeuMoDx™ RELEASE Solution.” <p>NeuMoDx_Novel_Dry_Reagent_2017.pdf (Exhibit 80)</p> <ul style="list-style-type: none"> “Three types of molecular diagnostic reagents were dried using unique formulations of select excipients: 1) Extraction reagents including magnetic particles with a nucleic acid affinity matrix, lytic enzymes, and encapsulated DNA/process controls.”

Claim	Claim Language	Infringement Evidence																																																																														
		<div><div>ACCELERATED STABILITY OF NMDx EXTRACTION PLATES</div><div></div><table><tr><th>assay @ 40°C</th><th>0</th><th>6</th><th>20</th><th>34</th><th>48</th><th>64</th><th>77</th><th>81</th><th>AVG</th><th>So</th><th>ICV</th></tr><tr><td>HCV</td><td>29.12</td><td>29.27</td><td>29.67</td><td>30.3</td><td>30.87</td><td>31.36</td><td>30.42</td><td>29.30</td><td>30.08</td><td>0.8a</td><td>2.8</td></tr><tr><td>SPC2</td><td>29.22</td><td>29.80</td><td>30.16</td><td>29.62</td><td>29.47</td><td>29.91</td><td>28.6a</td><td>29.3a</td><td>29.61</td><td>0.3</td><td>1</td></tr><tr><td>GeS</td><td>2a.84</td><td>2a.84</td><td>2a.3e</td><td>2a.37</td><td>2a.3</td><td>2a.44</td><td>2.63</td><td>2a.84</td><td>2a.81</td><td>0.33</td><td>1.3</td></tr><tr><td>SPC1</td><td>29.92</td><td>30.34</td><td>29.94</td><td>30.1</td><td>30.47</td><td>30.31</td><td>30.18</td><td>30.44</td><td>30.2</td><td>0.21</td><td>0.7</td></tr></table><div><div>eq @ 22°C (wks)</div><table><tr><th></th><th>0</th><th>3.4</th><th>11.4</th><th>14.6</th><th>27.4</th><th>27.4</th><th>44</th><th>a2</th></tr><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table></div><p>NMDx extraction plate is designed to be used on the NeuMoDx Molecular System to lyse bacteria and virus pathogens and capture DNA/RNA. It contains proteinase K, magnetic particles and DNA/RNA sample process control (SPC). The reagents were dried in a 24 well plate using the NMDx standard procedure, vacuum sealed foil pouch and stored at 40°C for accelerated study. The efficiency of the dried reagents was evaluated with two assays, Group B strep in Lim Broth and HCV in BaseMatrix. After equivalent to 1 yr at 22°C, no loss in activities was observed based on Ct and EPR values.</p></div> <div>US9050594 (Exhibit 24)</div> <div><ul style="list-style-type: none">Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a</div>	assay @ 40°C	0	6	20	34	48	64	77	81	AVG	So	ICV	HCV	29.12	29.27	29.67	30.3	30.87	31.36	30.42	29.30	30.08	0.8a	2.8	SPC2	29.22	29.80	30.16	29.62	29.47	29.91	28.6a	29.3a	29.61	0.3	1	GeS	2a.84	2a.84	2a.3e	2a.37	2a.3	2a.44	2.63	2a.84	2a.81	0.33	1.3	SPC1	29.92	30.34	29.94	30.1	30.47	30.31	30.18	30.44	30.2	0.21	0.7		0	3.4	11.4	14.6	27.4	27.4	44	a2									
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Claim	Claim Language	Infringement Evidence
		<p>biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 24. The system of claim 23, further comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample, a lysing reagent, and a sample process control, wherein the capture plate facilitates production of at least one biological sample combined with magnetic beads; an assay strip comprising at least one reagent well containing molecular diagnostic reagent volume configured to be combined with a nucleic acid volume of the set of nucleic acid volumes to produce at least one nucleic acid-reagent mixture; and a liquid handling system configured to transfer at least one biological sample combined with magnetic beads from the capture plate to the molecular diagnostic module, transfer at least one nucleic acid-reagent mixture from the assay strip back to the molecular diagnostic module. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”)

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at col. 3:14-28 (“In one example workflow of the system 100, a liquid handling system 250 aspirates a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), and dispenses the set of biological samples into a capture plate 110 to be lysed and combined with magnetic beads (containing a proprietary affinity coating to bind the nucleic acids to the magnetic beads) by a capture plate module 120. The liquid handling system 250 then aspirates substantially all of each sample of the set of lysed biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate no, and dispenses the set of magnetic bead-samples into a microfluidic cartridge 210, aligned within a cartridge receiving module 140 of a molecular diagnostic module 130, and configured to be manipulated by the molecular diagnostic module 130.”) U.S. Patent No. 9,050,594 col. 4:15-25 (“The set of wells 112 of the capture plate substrate 111 function to receive at least one biological sample which con-tain or are suspected of potentially containing nucleic acids, and to facilitate combination of the biological sample with a set of magnetic beads 119. Preferably, the wells 113 are each configured to accommodate not only a biological sample, but also to facilitate mixing of the biological sample with a set of magnetic beads 119 (e.g., using a pipettor, the liquid handling system 250 or other apparatus), which preferably are pre-loaded in wells 112, or alternatively may be added by an operator”) <p>US9339812 (Exhibit 26)</p> <ul style="list-style-type: none"> Claim 2: The method of claim 1, further comprising combining the biological sample with a quantity of magnetic beads, to produce a magnetic bead-sample mixture, prior to dispensing the biological sample into the fluidic pathway through the sample port. Claim 15. A method for processing and detecting nucleic acids from a set of biological samples with a cartridge having a set of fluidic pathways defined by an elastomeric layer, the method comprising: combining each biological sample of the set of biological samples with a quantity of magnetic beads to produce a set of nucleic acid-magnetic bead samples; aligning the cartridge at a cartridge platform of a molecular diagnostic module, the cartridge platform having a set of slots, and the molecular diagnostic module having a cam module contacting a set of pins aligned with the set of slots; transferring substantially all of each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways; moving the cam module by transitioning the actuator into an extended configuration, thereby displacing a subset of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the

Claim	Claim Language	Infringement Evidence
		<p>elastomeric layer to occlude at least one fluidic pathway of the set of fluidic pathways at a subset of occlusion positions for controlling a flow through the fluidic pathway; and detecting nucleic acids using a set of detection chambers coupled to the set of fluidic pathways.</p> <ul style="list-style-type: none"> • Claim 18. The method of claim 15, wherein combining each biological sample of the set of biological samples with a quantity of magnetic beads comprises combining each biological sample of the set of biological samples with a quantity of magnetic beads treated to be at least one of positively charged, magnetic, paramagnetic, and supraparamgetic [sic].” • Claim 29. A method for processing and detecting nucleic acids within a cartridge having a fluidic pathway including a set of occlusion positions defined by an elastomeric layer of the cartridge, the method comprising: aligning the cartridge at a cartridge platform of a molecular diagnostic module, the cartridge platform having a set of slots, and the molecular diagnostic module having a cam module contacting a set of pins aligned with the set of slots and an actuator that provides relative displacement between the cartridge platform and the set of pins; moving the cam module by transitioning the actuator into an extended configuration, thereby displacing a first sub-set of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the elastomeric layer to occlude the fluidic pathway at a first subset of the set of occlusion positions, thus defining a first truncated fluidic pathway passing through a magnetic field for controlling a flow through the fluidic pathway; capturing a sample of nucleic acids bound to magnetic beads within the first truncated fluidic pathway, by the magnetic field; and moving the cam module, thereby displacing a second subset of the set of pins through the set of slots of the cartridge platform and thereby manipulating the elastomeric layer to occlude the fluidic pathway, through the elastomeric layer, at a second subset of the set of occlusion positions, thus defining a second truncated fluidic pathway containing the sample of nucleic acids bound to magnetic beads. • U.S Patent No. 9,339,812 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular

Claim	Claim Language	Infringement Evidence
		<p>diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,339,812 at col. 3:14-20 (“In one example workflow of the system 100, a liquid handling system 250 aspirates a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), and dispenses the set of biological samples into a capture plate 110 to be lysed and combined with magnetic beads (containing a proprietary affinity coating to bind the nucleic acids to the magnetic beads) by a capture plate module 120.”) U.S. Patent No. 9,339,812 at col. 4:15-25 (“The set of wells 112 of the capture plate substrate 111 function to receive at least one biological sample which contain or are suspected of potentially containing nucleic acids, and to facilitate combination of the biological sample with a set of magnetic beads 119. Preferably, the wells 113 are each configured to accommodate not only a biological sample, but also to facilitate mixing of the biological sample with a set of magnetic beads 119 (e.g., using a pipettor, the liquid handling system 250 or other apparatus), which preferably are pre-loaded in wells 112, or alternatively may be added by an operator.”) <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound

Claim	Claim Language	Infringement Evidence
		<p>nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 4. The method of claim 3, wherein incubating the moiety-sample mixture comprises heating the moiety-sample solution to a temperature in the range of 25-95° C. for 5-60 minutes, thus simultaneously lysing the biological sample and facilitating binding of nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles. • Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the microfluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20 uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction. • Claim 19. A method for nucleic acid isolation from a biological sample, comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution includes a set of affinity moiety-coated microparticles, comprising a set of microparticles amide-bonded to at least one of poly(allylamine) of molecular weight <30,000 Da and Polypropylenimine tetramine dendrimer Generation 1; producing a moiety-sample mixture upon combination of the binding moiety solution with the biological sample; producing a set of moiety-bound nucleic acid particles upon incubation of the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a

Claim	Claim Language	Infringement Evidence
		<p>second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of the set of pins includes reversing displacement of at least one pin of the first subset of the set of pins, and reversing occlusion of a portion of the fluidic pathway.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at col. 3:35-43 (“The method 100 can be performed in any container or process chamber that is configured to contain a suitable concentration of affinity moiety-coated microparticles, facilitate suitable buffer conditions to allow for binding (e.g., buffer conditions providing a suitably low pH), contain suitable amounts of proteolytic or other enzymes for effective lysis or removal of inhibitory substances, and provide suitable thermal conditions that collectively enable binding of nucleic acids to the affinity moiety-coated microparticles.”) • U.S. Patent No. 9,382,532 at 4:35-55 (“In a specific example of this variation of Step S110, the microparticles are magnetic beads (e.g., magnetic, paramagnetic, superparamagnetic) with any suitable hydrophilicity (e.g., hydrophobic, hydrophilic), wherein the magnetic beads are coated with the affinity moiety and simultaneously received within the process chamber along with a low-pH buffer solution, proteolytic enzymes, and lytic reagents. In this specific example, magnetic separation can be used to facilitate further processing and isolation of nucleic acids bound to the affinity moieties coupled to magnetic beads. In another specific example of this variation, the microparticles are beads of a suitable size coated with the affinity moiety, and are simultaneously received within the process chamber along with a suitable buffer solution, proteolytic enzymes, and lytic reagents. In this specific example, sized-based separation can be used to facilitate further processing and isolation of nucleic acids bound to the affinity moieties coupled to the suitably-sized beads. The binding moiety solution of Step S110 can additionally or alternatively comprise any suitable affinity moiety or combination of affinity moiety delivered by any suitable mechanism or substrate.”) • U.S. Patent No. 9,382,532 at 4:56-5:2 (“Step S120 recites mixing the binding moiety solution with a biological sample, within the process chamber, in order to produce a moiety-sample solution, which functions to initiate lysis of the biological sample and enable target nucleic acids to bind to affinity moieties of the binding moiety solution. Preferably, binding of target nucleic acids to affinity moieties is facilitated by the appropriate pH of the binding solution, as shown in FIG. 1C; however, binding can

Claim	Claim Language	Infringement Evidence
		<p>be facilitated by any other suitable mechanism. In a variation involving an appropriate pH in the binding solution, mixing and binding can occur at a low pH, which produces a positively charged affinity moiety that is attracted to negatively charged nucleic acid molecules. Specific examples of affinity moieties that function via a pH shift are described in Section 2 below.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at 5:3-7(“In Step S120, the process chamber can be any suitable vessel, as shown in FIG. 1A, or a suitable capture plate, such as that described in U.S. patent application Ser. No. 13/766,359, entitled “System and Method for Processing and Detecting Nucleic Acids”, as shown in FIG. 1B.”) • U.S. Patent No. 9,382,532 at 5:42-6:2 (“ Step S130 recites incubating the moiety-sample solution during a time window, and functions to produce a lysed moiety-sample solution comprising a moiety-bound nucleic acid volume (e.g., a volume of nucleic acids reversibly bonded to the set of affinity moiety-coated microparticles) and a waste volume. In Step S130, the moiety-sample solution can be incubated using any suitable heating apparatus, as shown in FIG. 1A, or a suitable capture plate heater, such as that described in U.S. patent application Ser. No. 13/766,359, entitled "System and Method for Processing and Detecting Nucleic Acids", as shown in FIG. 1B. In Step S130, the nucleic acid is released from within the cell or other structure that it is contained within, and binds to the microparticles coupled with the affinity moiety, while other unbound components form a waste volume for later removal, as shown in FIG. 1 C. Preferably, the process chamber containing the moiety-sample solution (e.g., lysis, clean-up, binding reagents and the biological sample) is incubated for a defined period of time at a temperature preferably in the range of 25-95 C, wherein time and temperature parameters are biological sample-dependent. Example parameters for different biological samples are described briefly below, and further in Section 3 below. Alternatively, the moiety-sample solution can be transferred to another vessel for incubation in variations of Step S130. Furthermore, in variations of Steps S110, S120, and S130, any or all of the lysis, proteolytic and binding steps can occur simultaneously in the process chamber or any other suitable vessel, and are not required to be discrete steps.”) • U.S. Patent No. 9,050,594 at col. 28:34-38 (“Step S420 recites heating the set of magnetic bead-sample mixtures to produce a set of nucleic acid-magnetic bead samples, and functions to incubate the set of magnetic bead-sample mixtures in order to lyse biological matter, and release nucleic acids to be bound to magnetic beads.”) <p>US9441219 (Exhibit 53)</p>

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • Claim 7: The molecular diagnostic module of claim 1, further comprising: a capture plate comprising a well containing a set of magnetic beads, a lysing reagent, and a sample process control, configured to be combined with the biological sample, wherein the capture plate facilitates production of a magnetic bead-sample from the biological sample and the set of magnetic beads; an assay strip comprising a reagent well containing a molecular diagnostic reagent volume configured to be combined with the nucleic acid volume processed from the magnetic-bead sample, thereby generating a nucleic acid-reagent mixture; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the cartridge, transfer the nucleic acid volume from the cartridge to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip back to the cartridge. • Claim 14. The system of claim 8, further comprising a capture plate comprising a well containing a set of magnetic beads, a lysing reagent, and a sample process control, configured to be combined with the biological sample, wherein the capture plate facilitates production of a magnetic bead-sample from the biological sample and the set of magnetic beads; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the cartridge, and configured to transfer a nucleic acid volume processed from the magnetic bead-sample from the cartridge. • U.S. Patent No. 9,441,219 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation Subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical Subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) • U.S. Patent No. 9,441,219 at col. 4:23-33 (“The set of wells 112 of the capture plate substrate 111 function to receive at least one biological sample which contain or are suspected of potentially containing nucleic acids, and to facilitate combination of the biological sample with a set of magnetic beads 119. Preferably, the wells 113 are each configured to accommodate not only a biological sample, but also to facilitate mixing of the biological sample with a set of magnetic beads

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		<p>119 (e.g., using a pipettor, the liquid handling system 250 or other apparatus), which preferably are preloaded in wells 112, or alternatively may be added by an operator.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,441,219 at col. 27:42-67 (“An embodiment of a method 400 for processing and detecting nucleic acids from a set of biological samples comprises: combining each biological sample of the set of biological samples with a quantity of magnetic beads to produce a set of magnetic bead-sample mixtures S410; heating the set of magnetic bead-sample mixtures to produce a set of nucleic acid-magnetic bead samples S420; transferring each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways S430; producing a set of nucleic acid volumes from the set of nucleic acid-magnetic bead samples S440; combining each nucleic acid volume of the set of nucleic acid volumes with a molecular diagnostic reagent of a set of molecular diagnostic reagents to produce a set of nucleic acid-reagent mixtures S450; transferring each of the set of nucleic acid-reagent mixtures, through the corresponding fluidic pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers S460; and receiving light from the set of nucleic acid-reagent mixtures S470. The method 400 may further comprise generating a set of data based on light received from the set of nucleic acid-reagent mixtures S480. The method 400 functions to isolate and extract a set of nucleic acid volumes from a biological sample, and to facilitate analysis of the nucleic acid volumes according to at least one molecular diagnostic protocol.”) U.S. Patent No. 9,441,219 at col. 29:10-19 (“Step S420 recites heating the set of magnetic bead-sample mixtures to produce a set of nucleic acid-magnetic bead samples, and functions to incubate the set of magnetic bead-sample mixtures in order to lyse biological matter, and release nucleic acids to be bound to magnetic beads. Preferably, Step S420 comprises heating a capture plate containing the set of magnetic bead-sample mixtures for a specified amount of time at a specified temperature, and may additionally include cooling the set of magnetic bead-sample mixtures.”) <p>US9604213 (Exhibit 30)</p> <ul style="list-style-type: none"> Claim 1: A system for processing and detecting nucleic acids in cooperation with a cartridge comprising a heating region defined at a first surface, and a magnet housing region defined at a second surface in thermal communication with the first surface, the system comprising: a capture plate configured to facilitate combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate and separate nucleic acids from the set of magnetic beads,

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		<p>comprising: a cartridge platform configured to receive the cartridge and comprising a magnet receiving slot aligned with the second surface during operation, a heater configured to transmit heat to the heating region at the first surface during operation, and a magnet coupled to a magnet heating element that heats the magnet during operation with the magnet proximal the second surface, the magnet configured to pass through the magnet receiving slot into the magnet housing region during operation, thereby facilitating separation of a nucleic acid volume from the magnetic bead-sample and heating of the magnetic bead-sample in cooperation with the heater.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,604,213 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling Subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation Subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical Subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay Strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) • U.S. Patent No. 9,604,213 at col. 3:62-66 (“As shown in FIGS. 3A and 3B, the capture plate 110 comprises a capture plate substrate in comprising a set of wells 112 and a puncturable foil seal 115, and functions to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119.”) • U.S. Patent No. 9,604,213 at col. 4:23-33 (“The set of wells 112 of the capture plate substrate in function to receive at least one biological sample which contain or are suspected of potentially containing nucleic acids, and to facilitate combination of the biological sample with a set of magnetic beads 119. Preferably, the wells 113 are each configured to accommodate not only a biological sample, but also to facilitate mixing of the biological sample with a set of magnetic beads 119 (e.g., using a pipettor, the liquid handling system 250 or other apparatus), which preferably are preloaded in wells 112, or alternatively may be added by an operator.”) <p>US1001888 (Exhibit 55)</p> <ul style="list-style-type: none"> • Claim 14: A method for processing and detecting nucleic acids from a sample with a cartridge

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		<p>including a fluidic pathway passing between a heating region of the cartridge and a magnet housing region of the cartridge, wherein the method comprises: with a liquid handling system, combining the sample with a quantity of magnetic beads to produce a nucleic acid-magnetic bead sample; with the liquid handling system, transferring the nucleic acid-magnetic bead sample to the fluidic pathway of the cartridge; and contemporaneously transmitting heat through the heating region, by way of a heater, and transmitting heat through the magnet housing region, by way of a magnet heating element coupled to a magnet, thereby facilitating capture of nucleic acids of the sample at the fluidic pathway of the cartridge.</p> <ul style="list-style-type: none"> • U.S. Patent 10,010,888 at col. 4:29-39 (“The set of wells 112 of the capture plate substrate 111 function to receive at least one biological sample which contain or are suspected of potentially containing nucleic acids, and to facilitate combination of the biological sample with a set of magnetic beads 119. Preferably, the wells 113 are each configured to accommodate not only a biological sample, but also to facilitate mixing of the biological sample with a set of magnetic beads 119 (e.g., using a pipettor, the liquid handling system 250 or other apparatus), which preferably are preloaded in wells 112, or alternatively may be added by an operator.”) • U.S. Patent No. 10,010,88 at col. 6:15-29 (“An embodiment of the system 100 may further comprise a capture plate module 120, as shown in FIG. 4, which functions to receive, support, and heat a capture plate 110. The capture plate module 120 preferably comprises a thermally conducting substrate 121 configured to cradle a capture plate 110, a capture plate heater 123, a capture plate receiving module 125, and a capture plate electronics module 127. Preferably, the capture plate module 120 functions to facilitate lysis of a biological sample deposited into a well 113 of the capture plate, and to facilitate binding of nucleic acids (i.e., within a lysed biological sample) to a quantity of magnetic beads 119 within a well 113 of the capture plate 110. In a specific example, the capture plate module 120 has dimensions of 108 mmx156 mmx45 mm and is configured to rest on a flat surface.”)
1(h)	the plurality of magnetic binding particles comprising polycationic molecules on the surface thereof,	<p>The accused workflow comprises contacting the polynucleotides with a plurality of magnetic binding particles in the lysing container, the plurality of magnetic binding particles comprising polycationic molecules on the surface thereof.</p> <p>On information and belief, the accused system comprises contacting the polynucleotides with a plurality of magnetic binding particles in the lysing container, the plurality of magnetic binding particles comprising polycationic molecules on the surface thereof.</p>

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		<p>US9339812 (Exhibit 26)</p> <ul style="list-style-type: none"> Claim 18. The method of claim 15, wherein combining each biological sample of the set of biological samples with a quantity of magnetic beads comprises combining each biological sample of the set of biological samples with a quantity of magnetic beads treated to be at least one of positively charged, magnetic, paramagnetic, and supraparamagnetic [sic].” U.S. Patent No. 9,339,812 at col: 4:42-49 (“The magnetic beads are preferably polymer beads, precoupled with a ligand for binding to a nucleic acid, and comprising a superparamagnetic [sic] component. Additionally, the magnetic beads may be treated to be positively charged. However, the magnetic beads may alternatively be any appropriate magnetic beads (e.g. magnetic, paramagnetic [sic], or superparamagnetic) configured to facilitate biomagnetic separation.”) U.S. Patent No. 9,339,812 at col. 27:50-56 (“The magnetic beads are preferably polymer beads, precoupled with a ligand for binding to a nucleic acid, and comprising a Superparamagnetic component. Additionally, the magnetic beads may be treated to be positively charged. However, the magnetic beads may alternatively be any appropriate magnetic beads configured to facilitate biomagnetic separation.”) <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of pins, wherein displacement of the second subset of pins includes reversal of

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		<p>displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 2. The method of claim 1, wherein receiving the binding moiety solution, comprising the set of affinity moiety-coated microparticles, within the process chamber comprises receiving a set of magnetic microparticles, each magnetic microparticle modified with an amine-reactive ester functional group configured to react with one of a set of amine groups of a molecule of Polypropylenimine tetramine dendrimer Generation 1. • Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the microfluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20 uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction. • Claim 19. A method for nucleic acid isolation from a biological sample, comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution includes a set of affinity moiety-coated microparticles, comprising a set of microparticles amide-bonded to at least one of poly(allylamine) of molecular weight <30,000 Da and Polypropylenimine tetramine dendrimer Generation 1; producing a moiety-sample mixture upon combination of the binding moiety solution with the biological sample; producing a set of moiety-bound nucleic acid particles upon incubation of the moiety-sample mixture to reversibly bind nucleic acid material of the biological

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		<p>sample to the set of affinity moiety-coated microparticles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of the set of pins includes reversing displacement of at least one pin of the first subset of the set of pins, and reversing occlusion of a portion of the fluidic pathway.</p> <ul style="list-style-type: none"> U.S. Patent No. 9,382,532 at 4:56-5:2 (“Step S120 recites mixing the binding moiety solution with a biological sample, within the process chamber, in order to produce a moiety-sample solution, which functions to initiate lysis of the biological sample and enable target nucleic acids to bind to affinity moieties of the binding moiety solution. Preferably, binding of target nucleic acids to affinity moieties is facilitated by the appropriate pH of the binding solution, as shown in FIG. 1C; however, binding can be facilitated by any other suitable mechanism. In a variation involving an appropriate pH in the binding solution, mixing and binding can occur at a low pH, which produces a positively charged affinity moiety that is attracted to negatively charged nucleic acid molecules. Specific examples of affinity moieties that function via a pH shift are described in Section 2 below.”) U.S. Patent No. 9,382,532 at 9:9-30 (“In one variation of Step S160, the affinity moieties, examples of which are described in Section 2 below, function based upon the pH of the environment. Specifically, at low pH, the affinity moieties are positively charged, which results in attraction to negatively charged nucleic acids; however, at high pH, the affinity moieties are negatively charged, which results in repulsion of negatively charged nucleic acids. In a specific example of this variation, releasing the nucleic acid sample comprises providing an elution solution that is in the range of pH 12- pH 13 to effect efficient elution/release of the bound target nucleic acid(s) from the microparticle based upon a shift to a more basic pH. In the specific example, the elution solution comprises 20 mM of NaOH; however, in other variations the elution solution can comprise any other suitable concentration of NaOH or KOH, depending upon the application (e.g., sample type). Again, substantial removal of the wash solution during variations of the method 100 comprising Step S150 can facilitate or enhance the pH-shift for nucleic acid release, as the wash solution can potentially neutralize the elution solution in an undesirable manner and mitigate the elevated pH necessary for releasing the target nucleic

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		<p>acid(s).”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,382,532 at 11:30-40 (“Nucleic acid molecules are typically negatively charged at standard processing conditions. In such processes, positively charged moieties can capture and retain the negatively charged nucleic acid molecules; however, the positively charged moieties can bind too strongly with target nucleic acids leading to an irreversible process whereby the bound nucleic acid cannot be released into the solution for further processing/analysis. Two novel molecules that are capable of binding nucleic acid in a reversible manner are described below, wherein the reversible binding is modulated by changing the pH of the environment.”) U.S. Patent No. 9,382,532 at 11:43-53 (“Poly(allylamine)), or PAA, is a cationic poly electrolyte prepared by the polymerization of allylamine. Allylamine is an organic compound with the formula <div data-bbox="1717 613 1879 755" data-label="Chemical-Block"> </div> <p>C₃H₅NH₂. An exemplary PAA molecule has the following formula: <div data-bbox="1911 755 1942 787" data-label="Text">”)</div> </p> U.S. Patent No. 9,382,532 at 12:11-27 (“Polypropylenimine tetramine dendrimer Generation 1, or DABAM Generation 1, is a cationic polyelectrolyte dendrimer. Dendrimers are repetitively branched molecules. A dendrimer is typically symmetric around a core, and often adopts a spherical three-dimensional structure. An exemplary DABAM molecule has the following formula: <div data-bbox="720 954 1423 1177" data-label="Chemical-Block"> </div> <p>”)</p> U.S. Patent No. 9,382,532 at 12:51-61 (“The affinity moieties, such as the PAA and DABAM described in Section 2.1 and 2.2, can be immobilized on a suitable substrate to facilitate subsequent capture of target nucleic acids bound to the substrate (e.g., by magnetic separation, size-based separation, density-based separation, or focusing). A process for coupling the affinity moiety to the substrate preferably relies on creation of a covalent bond between the affinity moiety and

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		<p>the microparticle, and in one variation as described below, a carboxylic acid group (-COOH) can be used to form the covalent bond between the microparticles and the affinity moieties.”</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at 12:62-13:13 (“As shown in FIG. 3, a method 200 for coupling the microparticles with the affinity moieties comprises activating carboxylated microparticles with EDAC 5210 to form a set of microparticle-reactive ester compounds; treating the set of microparticle-reactive ester compounds with an N-Hydroxysuccinimide to form a set of microparticle-amine reactive ester compounds S220, combining the set of microparticle-amine reactive ester compounds with a set of affinity moieties selected from the group comprising PAA and DABAM S230 to produce a microparticle-moiety solution; and washing the microparticle-moiety solution, thereby producing a set of microparticles covalently bonded to the set of affinity moieties by amide bonds S240. The method 200 functions to produce a set of moiety-bound microparticles for nucleic acid isolation. Preferably, the microparticles are magnetic to facilitate nucleic acid isolation by magnetic separation; however, the microparticles can alternatively be characterized by any suitable feature that facilitates nucleic acid isolation, as described earlier in Section 1.”) • U.S. Patent No. 9,382,532 at 13:14-28 (“In a specific example, as shown in FIG. 3, the method 200 comprises activating magnetic carboxylated microparticles with EDAC in Step S110 to form a set of magnetic microparticle-reactive ester compounds; treating the set of magnetic microparticle-reactive ester compounds with a N-Hydroxysulfosuccinimide to form a set of microparticle-amine reactive ester compounds S220; combining the set of microparticle-amine reactive ester compounds with a set of affinity moieties selected from the group comprising PAA of molecular weight less than 30,000 Da and DABAM of generation less than two S230 to produce a microparticle-moiety solution; and repeatedly washing the microparticle-moiety solution, thereby producing a set of magnetic microparticles covalently bonded to the set of affinity moieties by amide bonds S240.”) • U.S. Patent No. 9,382,532 at 13:42-45 (“A first example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, cerebrospinal fluid (CSF) as a representative biological sample, and Enterovirus (EV) viral particles as the model target.”) • U.S. Patent No. 9,382,532 at 14:5-9 (“A second example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, M4 transport medium containing a nasal swab (donor) as a representative biological sample, and Enterovirus (EV) viral particles as the model target.”) • U.S. Patent No. 9,382,532 at 14:41-45 (“A third example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, Universal Transport Medium (UTM)

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		<p>containing a nasal swab (donor) as a representative biological sample, and Enterovirus (EV) viral particles as the model target.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at 15:8-12 (“A fourth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, M4 transport medium containing nasal swab (donor) as a representative biological sample, and Enterovirus (EV) viral particles as the model target.”) • U.S. Patent No. 9,382,532 at 15:59-63 (“A fifth example of the method 100 comprises using DABAM affinity moieties coated onto magnetic microparticles, Human Urine (donor), Human Plasma and Buccal Swab (donor) as representative biological sample matrices, and Group B Streptococcus (GBS) DNA (ATCC, Virginia) as the model target.”) • U.S. Patent No. 9,382,532 at 16:29-32 (“A sixth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, Human Urine (donor) as a representative biological sample, and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,382,532 at 16:61-65 (“A seventh example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, Human Plasma (donor, obtained from Bioreclamation, Inc.) as a representative biological sample, and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,382,532 at 17:27-31 (“An eighth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, simulated swab specimens as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,382,532 at 17:60-64 (“A ninth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, simulated swab transport media specimens as representative biological samples and Group B Streptococcus (GBS) DNA at the model target.”) • U.S. Patent No. 9,382,532 at 18:31-34 (“A tenth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, whole blood as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,382,532 at 19:12-15 (“An eleventh example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, Urine (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,382,532 at 19:46-49 (“A twelfth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, plasma (donor) as a representative biological sample, and Group B Streptococcus (GBS) DNA as the model target.”)

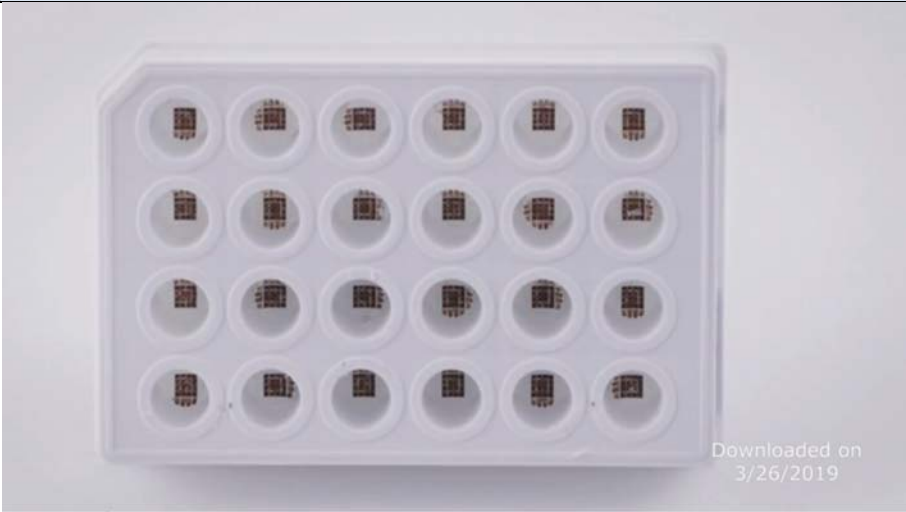
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		<ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at 20:6-11 (“A thirteenth example of the method 100, demonstrating the effect of binding time, comprises using PAA affinity moieties coated onto magnetic microparticles, Human Plasma (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA (ATCC, Virginia) as the model target.”) • U.S. Patent No. 9,382,532 at 20:33-38 (“A fourteenth example of the method 100, demonstrating the effect of binding temperature, comprises using PAA affinity moieties coated onto magnetic microparticles, Human Plasma (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA (ATCC, Virginia) as the model target.”) • U.S. Patent No. 9,382,532 at 21:23-27 (“A fifteenth example of the method 100, demonstrating the effect of binding temperature, comprises using PAA affinity moieties coated onto magnetic microparticles, Urine (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,382,532 at 21:58-62 (“A sixteenth example of the method 100, demonstrating the use of two different elution solutions, comprises using PAA affinity moieties coated onto magnetic microparticles, Human Urine (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,382,532 at 22:31-37 (“A seventeenth example of the method 100, demonstrating the use of nucleic acid isolation reagents for total nucleic acid (TNA) extraction, comprises using PAA affinity moieties coated onto magnetic microparticles, M4 transport media as a representative biological sample, and Enterovirus (EV) viral particles as the model RNA target and Group B Streptococcus DNA as model DNA target.”) <p>US9540636 (Exhibit 54)</p> <ul style="list-style-type: none"> • Claim 2. The method of claim 1, wherein the set of affinity moiety-coated microparticles comprises a set of magnetic microparticles, and wherein receiving the binding moiety solution, comprising the set of affinity moiety-coated microparticles, within the process chamber comprises receiving the set of magnetic microparticles, each magnetic microparticle modified with an amine-reactive ester functional group configured to react with one of a set of amine groups of a molecule of Polypropylenimine tetramine dendrimer Generation 1. • Claim 19. The method of claim 17, wherein the set of affinity moiety-coated microparticles comprises a set of microparticles amide-bonded to at least one of the Poly(allylamine) of molecular weight <40,000 Da and the Polypropylenimine tetramine dendrimer Generation 1.

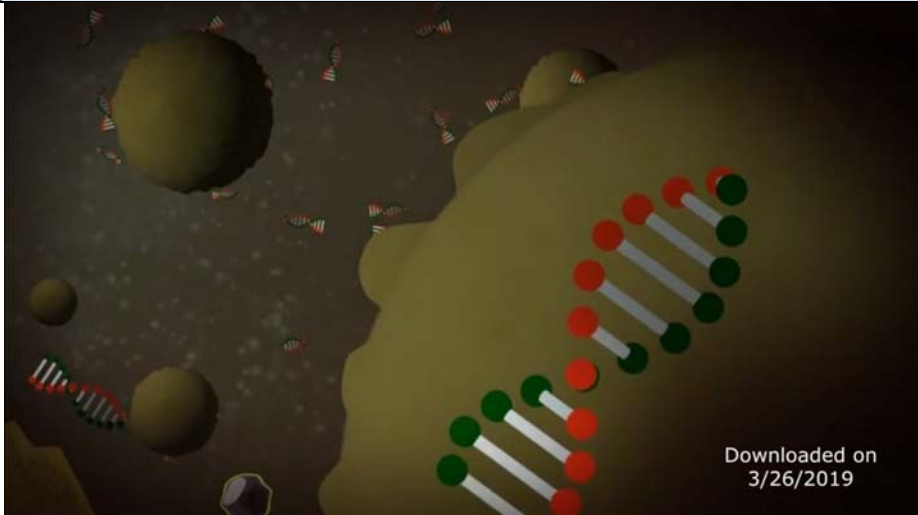
Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> U.S. Patent No. 9,540,636 at Abstract (“A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber; mixing the binding moiety solution with a biological sample, within the process chamber, in order to produce a moiety-sample mixture; incubating the moiety-sample mixture during a time window, thereby producing a solution comprising a set of moiety-bound nucleic acid particles and a waste volume; separating the set of moiety-bound nucleic acid particles from the waste volume; washing the set of moiety-bound nucleic acid particles; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles. The method preferably utilizes a binding moiety comprising at least one of poly(allylamine) and polypropylenimine tetramine dendrimer, both of which reversibly bind and unbind to nucleic acids based upon environmental pH.”) U.S. Patent No. 9,540,636 at col. 11:51-61 (“Nucleic acid molecules are typically negatively charged at standard processing conditions. In such processes, positively charged moieties can capture and retain the negatively charge nucleic acid molecules; however, the positively charged moieties can bind too strongly with target nucleic acids leading to an irreversible process whereby the bound nucleic acid cannot be released into the solution for further processing/analysis. Two novel molecules that are capable of binding nucleic acid in a reversible manner are described below, wherein the reversible binding is modulated by changing the pH of the environment.”) U.S. Patent No. 9,540,636 at col. 11:65-66 (“Poly(allylmine), or PAA, is a cationic polyelectrolyte prepared by the polymerization of allylamine.”) <div data-bbox="806 959 957 1109" data-label="Chemical-Block"> <p>The diagram shows the chemical structure of poly(allylamine) (PAA). It consists of a repeating unit enclosed in brackets with a subscript 'n'. The backbone is a carbon-carbon single bond. One carbon atom is bonded to a hydrogen atom (represented by a line pointing down and to the left) and a nitrogen atom (represented by a line pointing up and to the right). The nitrogen atom is bonded to a hydrogen atom (represented by a line pointing up and to the right). The other carbon atom is bonded to a hydrogen atom (represented by a line pointing down and to the right) and a hydrogen atom (represented by a line pointing up and to the right).</p> </div> <ul style="list-style-type: none"> U.S. Patent No. 9,540,636 at col.12:36-38 (“Polypropylenimine tetramine dendrimer Generation 1, or DABAM Generation 1, is a cationic polyelectrolyte dendrimer.”)

Claim	Claim Language	Infringement Evidence
		<div data-bbox="724 280 1428 503" data-label="Chemical-Block"> </div> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 14:9-12 (A first example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, cerebrospinal fluid (CSF) as a representative biological sample, and Enterovirus (EV) viral particles as the model target.”) • U.S. Patent No. 9,540,636 at col. 14:44-48 (“A second example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, M4 transport medium containing a nasal Swab (donor) as a representative biological sample, and Enterovirus (EV) viral particles as the model target.”) • U.S. Patent No. 9,540,636 at col. 15:18-22 (“A third example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, Universal Transport Medium (UTM) containing a nasal swab (donor) as a representative biological sample, and Enterovirus (EV) viral particles as the model target.”) • U.S. Patent No. 9,540,636 at col. 15:56-60 (“A fourth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, M4 transport medium containing nasal Swab (donor) as a representative biological sample, and Enterovirus (EV) viral particles as the model target.”) • U.S. Patent No. 9,540,636 at col. 16:43-48 (“A fifth example of the method 100 comprises using DABAM affinity moieties coated onto magnetic microparticles, Human Urine (donor), Human Plasma and Buccal Swab (donor) as representative biological sample matrices, and Group B Streptococcus (GBS) DNA (ATCC, Virginia) as the model target.”) • U.S. Patent No. 9,540,636 at col. 17:19-22 (“A sixth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, Human Urine (donor) as a representative biological sample, and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,540,636 at col. 17:56-60 (“A seventh example of the method 100 comprises using

Claim	Claim Language	Infringement Evidence
		<p>PAA affinity moieties coated onto magnetic microparticles, Human Plasma (donor, obtained from Bioreclamation, Inc.) as a representative biological sample, and Group B Streptococcus (GBS) DNA as the model target.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 18:26-31 (“An eighth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, simulated Swab specimens as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,540,636 at col. 18:65-19:2 (“A ninth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, simulated Swab transport media specimens as representative biological samples and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,540,636 at col. 19:41-44 (“A tenth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, whole blood as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,540,636 at col. 20:27-30 (“An eleventh example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, Urine (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,540,636 at col. 20:66-21:2 (“A twelfth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, plasma (donor) as a representative biological sample, and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,540,636 at col. 21:31-36 (“A thirteenth example of the method 100, demonstrating the effect of binding time, comprises using PAA affinity moieties coated onto magnetic microparticles, Human Plasma (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA (ATCC, Virginia) as the model target.”) • U.S. Patent No. 9,540,636 at col. 21:61-66 (“A fourteenth example of the method 100, demonstrating the effect of binding temperature, comprises using PAA affinity moieties coated onto magnetic microparticles, Human Plasma (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA (ATCC, Virginia) as the model target.”) • U.S. Patent No. 9,540,636 at col. 22:56-60 (“A fifteenth example of the method 100, demonstrating the effect of binding temperature, comprises using PAA affinity moieties coated onto magnetic microparticles, Urine (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target.”) • U.S. Patent No. 9,540,636 at col. 23:30-35 (“A sixteenth example of the method 100, demonstrating

Claim	Claim Language	Infringement Evidence
		<p>the use of two different elution solutions, comprises using PAA affinity moieties coated onto magnetic microparticles, Human Urine (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,540,636 at col. 24:10-16 (“A seventeenth example of the method 100, demonstrating the use of nucleic acid isolation reagents for total nucleic acid (TNA) extraction, comprises using PAA affinity moieties coated onto magnetic microparticles, M4 transport media as a representative biological sample, and Enterovirus (EV) viral particles as the model RNA target and Group B Streptococcus DNA as model DNA target.”)
1(i)	wherein at least a portion of the polynucleotides are retained on the plurality of magnetic binding particles in the lysate solution;	<p>The accused workflow comprises contacting the polynucleotides with a plurality of magnetic binding particles in the lysing container, the plurality of magnetic binding particles comprising polycationic molecules on the surface thereof, wherein at least a portion of the polynucleotides are retained on the plurality of magnetic binding particles in the lysate solution.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> <i>Id.</i> at 0:40 (showing the extraction plate).

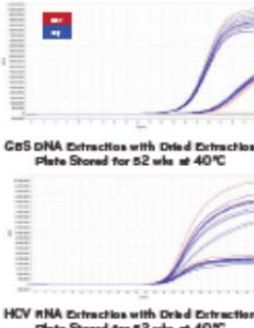
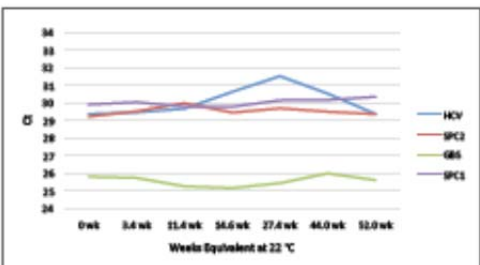
Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none"> • “Each extraction plate well is then autonomously heated for as little as six minutes to ensure proper lysing and binding of the nucleic acids to the paramagnetic beads. The temperatures applied range from 37° C to over 90° C, resulting in the flexibility to process a wide variety of DNA and RNA IVD and LDT tests simultaneously.” 1:07-1:32 • <i>Id.</i> at 1:16 (showing binding of nucleic acids to paramagnetic beads).

Claim	Claim Language	Infringement Evidence
		 <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound nucleic acid is eluted using the NeuMoDx™ RELEASE Solution. <p>40500098_D-IFU-NeuMoDx-Extraction-Plate-US-ONLY (Exhibit 59)</p> <ul style="list-style-type: none"> • “The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate lysis buffer in the NeuMoDx Extraction Plate and is subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres.” <i>Id.</i> at 1. • “The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution.” <i>Id.</i> at 1.

Claim	Claim Language	Infringement Evidence
		<p>40600100_Rev-D-IFU-NeuMoDx-WASH-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 58)</p> <ul style="list-style-type: none"> The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 20)</p> <ul style="list-style-type: none"> The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres. The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600103_Rev-D-IFU-NeuMoDx-Lysis-Buffer-4-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 66)</p> <ul style="list-style-type: none"> The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of enriched Lim Broth is mixed with NeuMoDx Lysis Buffer 4 and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres dried in the NeuMoDx Extraction Plate.

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600104_Rev-D-IFU-NeuMoDx-Lysis-Buffer-3-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 65)</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600105_Rev-D-IFU-NeuMoDx-Lysis-Buffer-2-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 64)</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600106_Rev-D-IFU-NeuMoDx-Lysis-Buffer-1-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 63)</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600129_D-IFU-GBS-Test-Strip-US-only.pdf (Exhibit 60)</p> <ul style="list-style-type: none"> “NeuMoDx™ GBS Test Strip: Instructions for Use...The released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are loaded in to the NeuMoDx™ Cartridge where the unbound, non-DNA components are further washed away with NeuMoDx™ WASH Solution and the bound DNA is eluted using NeuMoDx™ RELEASE Solution.” <p>40600145_-Rev-D-IFU-NeuMoD-LDT-Master-Mix-DNA-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 67)</p> <ul style="list-style-type: none"> “NeuMoDx™ LDT Master Mix, DNA: Instructions for Use...Upon lysis, the released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bund nucleic acids, are

Claim	Claim Language	Infringement Evidence
		<p>then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound DNA is eluted using NeuMoDx™ RELEASE Solution.”</p> <p>40600146_D-IFU-NeuMoDx-LDT-Master-Mix-RNA-US-ONLY (Exhibit 62)</p> <ul style="list-style-type: none"> • “NeuMoDx™ LDT Master Mix, RNA: Instructions for Use...Upon lysis, the released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound RNA is eluted using NeuMoDx™ RELEASE Solution.” <p>NeuMoDx_Novel_Dry_Reagent_2017.pdf (Exhibit 80)</p> <ul style="list-style-type: none"> • “Three types of molecular diagnostic reagents were dried using unique formulations of select excipients: 1) Extraction reagents including magnetic particles with a nucleic acid affinity matrix, lytic enzymes, and encapsulated DNA/process controls.”

Claim	Claim Language	Infringement Evidence																																																																								
		<div><div><p>ACCELERATED STABILITY OF NMDx EXTRACTION PLATES</p><table><tr><th>ct at 40°C</th><th>0</th><th>6</th><th>20</th><th>34</th><th>48</th><th>64</th><th>77</th><th>81</th><th>AVG</th><th>So</th><th>ICV</th></tr><tr><td>HCV</td><td>29.12</td><td>29.27</td><td>29.67</td><td>30.3</td><td>30.87</td><td>31.36</td><td>30.42</td><td>29.30</td><td>30.08</td><td>0.8a</td><td>2.8</td></tr><tr><td>SPC2</td><td>29.22</td><td>29.80</td><td>30.16</td><td>29.62</td><td>29.47</td><td>29.91</td><td>28.6a</td><td>29.3a</td><td>29.61</td><td>0.3</td><td>1</td></tr><tr><td>GeS</td><td>2a.84</td><td>2a.84</td><td>2a.3e</td><td>2a.37</td><td>2a.3</td><td>2a.44</td><td>2.63</td><td>2a.84</td><td>2a.81</td><td>0.33</td><td>1.3</td></tr><tr><td>SPC1</td><td>29.92</td><td>30.34</td><td>29.94</td><td>30.1</td><td>30.47</td><td>30.31</td><td>30.18</td><td>30.44</td><td>30.2</td><td>0.21</td><td>0.7</td></tr><tr><td>82 at 22°C (wks)</td><td>0</td><td>3.4</td><td>11.4</td><td>14.6</td><td>27.4</td><td>27.4</td><td>44</td><td>a2</td><td></td><td></td><td></td></tr></table><p>NMDx extraction plate is designed to be used on the NeuMoDx Molecular System to lyse bacteria and virus pathogens and capture DNA/RNA. It contains proteinase K, magnetic particles and DNA/RNA sample process control (SPC). The reagents were dried in a 24 well plate using the NMDx standard procedure, vacuum sealed foil pouch and stored at 40°C for accelerated study. The efficiency of the dried reagents was evaluated with two assays, Group B strep in Lim Broth and HCV in BaseMatrix. After equivalent to 1 yr at 22°C, no loss in activities was observed based on Ct and EPR values.</p></div></div> <div>US9050594 (Exhibit 24)</div> <div><ul style="list-style-type: none">Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a</div>	ct at 40°C	0	6	20	34	48	64	77	81	AVG	So	ICV	HCV	29.12	29.27	29.67	30.3	30.87	31.36	30.42	29.30	30.08	0.8a	2.8	SPC2	29.22	29.80	30.16	29.62	29.47	29.91	28.6a	29.3a	29.61	0.3	1	GeS	2a.84	2a.84	2a.3e	2a.37	2a.3	2a.44	2.63	2a.84	2a.81	0.33	1.3	SPC1	29.92	30.34	29.94	30.1	30.47	30.31	30.18	30.44	30.2	0.21	0.7	82 at 22°C (wks)	0	3.4	11.4	14.6	27.4	27.4	44	a2			
ct at 40°C	0	6	20	34	48	64	77	81	AVG	So	ICV																																																															
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Claim	Claim Language	Infringement Evidence
		<p>biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 24. The system of claim 23, further comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample, a lysing reagent, and a sample process control, wherein the capture plate facilitates production of at least one biological sample combined with magnetic beads; an assay strip comprising at least one reagent well containing molecular diagnostic reagent volume configured to be combined with a nucleic acid volume of the set of nucleic acid volumes to produce at least one nucleic acid-reagent mixture; and a liquid handling system configured to transfer at least one biological sample combined with magnetic beads from the capture plate to the molecular diagnostic module, transfer at least one nucleic acid-reagent mixture from the assay strip back to the molecular diagnostic module. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”)

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at col. 3:14-28 (“In one example workflow of the system 100, a liquid handling system 250 aspirates a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), and dispenses the set of biological samples into a capture plate 110 to be lysed and combined with magnetic beads (containing a proprietary affinity coating to bind the nucleic acids to the magnetic beads) by a capture plate module 120. The liquid handling system 250 then aspirates substantially all of each sample of the set of lysed biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate no, and dispenses the set of magnetic bead-samples into a microfluidic cartridge 210, aligned within a cartridge receiving module 140 of a molecular diagnostic module 130, and configured to be manipulated by the molecular diagnostic module 130.”) U.S. Patent No. 9,050,594 col. 4:15-25 (“The set of wells 112 of the capture plate substrate 111 function to receive at least one biological sample which con-tain or are suspected of potentially containing nucleic acids, and to facilitate combination of the biological sample with a set of magnetic beads 119. Preferably, the wells 113 are each configured to accommodate not only a biological sample, but also to facilitate mixing of the biological sample with a set of magnetic beads 119 (e.g., using a pipettor, the liquid handling system 250 or other apparatus), which preferably are pre-loaded in wells 112, or alternatively may be added by an operator”) <p>US9339812 (Exhibit 26)</p> <ul style="list-style-type: none"> Claim 2: The method of claim 1, further comprising combining the biological sample with a quantity of magnetic beads, to produce a magnetic bead-sample mixture, prior to dispensing the biological sample into the fluidic pathway through the sample port. Claim 15. A method for processing and detecting nucleic acids from a set of biological samples with a cartridge having a set of fluidic pathways defined by an elastomeric layer, the method comprising: combining each biological sample of the set of biological samples with a quantity of magnetic beads to produce a set of nucleic acid-magnetic bead samples; aligning the cartridge at a cartridge platform of a molecular diagnostic module, the cartridge platform having a set of slots, and the molecular diagnostic module having a cam module contacting a set of pins aligned with the set of slots; transferring substantially all of each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways; moving the cam module by transitioning the actuator into an extended configuration, thereby displacing a subset of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the

Claim	Claim Language	Infringement Evidence
		<p>elastomeric layer to occlude at least one fluidic pathway of the set of fluidic pathways at a subset of occlusion positions for controlling a flow through the fluidic pathway; and detecting nucleic acids using a set of detection chambers coupled to the set of fluidic pathways.</p> <ul style="list-style-type: none"> • Claim 18. The method of claim 15, wherein combining each biological sample of the set of biological samples with a quantity of magnetic beads comprises combining each biological sample of the set of biological samples with a quantity of magnetic beads treated to be at least one of positively charged, magnetic, paramagnetic, and supraparamgetic [sic].” • Claim 29. A method for processing and detecting nucleic acids within a cartridge having a fluidic pathway including a set of occlusion positions defined by an elastomeric layer of the cartridge, the method comprising: aligning the cartridge at a cartridge platform of a molecular diagnostic module, the cartridge platform having a set of slots, and the molecular diagnostic module having a cam module contacting a set of pins aligned with the set of slots and an actuator that provides relative displacement between the cartridge platform and the set of pins; moving the cam module by transitioning the actuator into an extended configuration, thereby displacing a first sub-set of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the elastomeric layer to occlude the fluidic pathway at a first subset of the set of occlusion positions, thus defining a first truncated fluidic pathway passing through a magnetic field for controlling a flow through the fluidic pathway; capturing a sample of nucleic acids bound to magnetic beads within the first truncated fluidic pathway, by the magnetic field; and moving the cam module, thereby displacing a second subset of the set of pins through the set of slots of the cartridge platform and thereby manipulating the elastomeric layer to occlude the fluidic pathway, through the elastomeric layer, at a second subset of the set of occlusion positions, thus defining a second truncated fluidic pathway containing the sample of nucleic acids bound to magnetic beads. • U.S Patent No. 9,339,812 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular

Claim	Claim Language	Infringement Evidence
		<p>diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,339,812 at col. 3:14-20 (“In one example workflow of the system 100, a liquid handling system 250 aspirates a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), and dispenses the set of biological samples into a capture plate 110 to be lysed and combined with magnetic beads (containing a proprietary affinity coating to bind the nucleic acids to the magnetic beads) by a capture plate module 120.”) U.S. Patent No. 9,339,812 at col. 4:15-25 (“The set of wells 112 of the capture plate substrate 111 function to receive at least one biological sample which contain or are suspected of potentially containing nucleic acids, and to facilitate combination of the biological sample with a set of magnetic beads 119. Preferably, the wells 113 are each configured to accommodate not only a biological sample, but also to facilitate mixing of the biological sample with a set of magnetic beads 119 (e.g., using a pipettor, the liquid handling system 250 or other apparatus), which preferably are pre-loaded in wells 112, or alternatively may be added by an operator.”) <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound

Claim	Claim Language	Infringement Evidence
		<p>nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 4. The method of claim 3, wherein incubating the moiety-sample mixture comprises heating the moiety-sample solution to a temperature in the range of 25-95° C. for 5-60 minutes, thus simultaneously lysing the biological sample and facilitating binding of nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles. • Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the microfluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20 uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction. • Claim 19. A method for nucleic acid isolation from a biological sample, comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution includes a set of affinity moiety-coated microparticles, comprising a set of microparticles amide-bonded to at least one of poly(allylamine) of molecular weight <30,000 Da and Polypropylenimine tetramine dendrimer Generation 1; producing a moiety-sample mixture upon combination of the binding moiety solution with the biological sample; producing a set of moiety-bound nucleic acid particles upon incubation of the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a

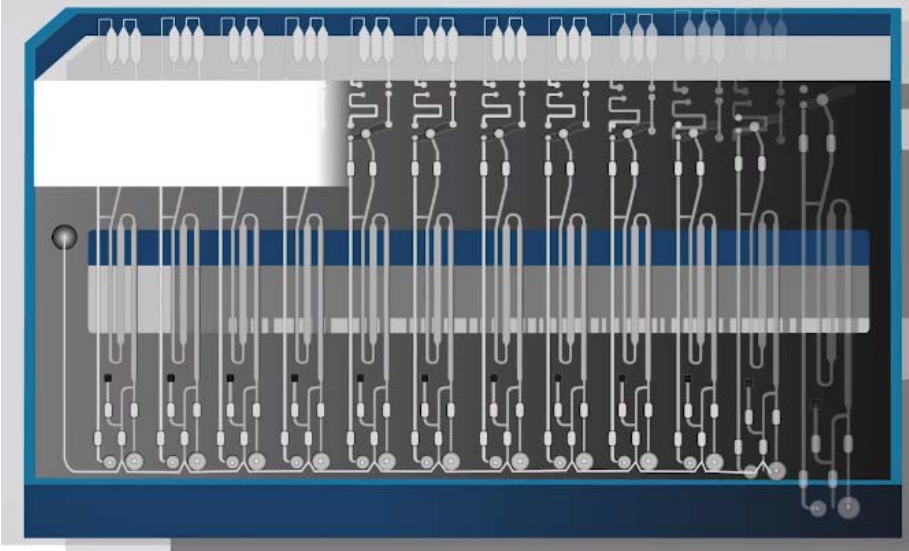
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		<p>second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of the set of pins includes reversing displacement of at least one pin of the first subset of the set of pins, and reversing occlusion of a portion of the fluidic pathway.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at col.3:35-43 (“The method 100 can be performed in any container or process chamber that is configured to contain a suitable concentration of affinity moiety-coated microparticles, facilitate suitable buffer conditions to allow for binding (e.g., buffer conditions providing a suitably low pH), contain suitable amounts of proteolytic or other enzymes for effective lysis or removal of inhibitory substances, and provide suitable thermal conditions that collectively enable binding of nucleic acids to the affinity moiety-coated microparticles.”) • U.S. Patent No. 9,382,532 at 4:35-55 (“In a specific example of this variation of Step S110, the microparticles are magnetic beads (e.g., magnetic, paramagnetic, superparamagnetic) with any suitable hydrophilicity (e.g., hydrophobic, hydrophilic), wherein the magnetic beads are coated with the affinity moiety and simultaneously received within the process chamber along with a low-pH buffer solution, proteolytic enzymes, and lytic reagents. In this specific example, magnetic separation can be used to facilitate further processing and isolation of nucleic acids bound to the affinity moieties coupled to magnetic beads. In another specific example of this variation, the microparticles are beads of a suitable size coated with the affinity moiety, and are simultaneously received within the process chamber along with a suitable buffer solution, proteolytic enzymes, and lytic reagents. In this specific example, sized-based separation can be used to facilitate further processing and isolation of nucleic acids bound to the affinity moieties coupled to the suitably-sized beads. The binding moiety solution of Step S110 can additionally or alternatively comprise any suitable affinity moiety or combination of affinity moiety delivered by any suitable mechanism or substrate.”) • U.S. Patent No. 9,382,532 at 4:56-5:2 (“Step S120 recites mixing the binding moiety solution with a biological sample, within the process chamber, in order to produce a moiety-sample solution, which functions to initiate lysis of the biological sample and enable target nucleic acids to bind to affinity moieties of the binding moiety solution. Preferably, binding of target nucleic acids to affinity moieties is facilitated by the appropriate pH of the binding solution, as shown in FIG. 1C; however, binding can


Claim	Claim Language	Infringement Evidence
		<p>be facilitated by any other suitable mechanism. In a variation involving an appropriate pH in the binding solution, mixing and binding can occur at a low pH, which produces a positively charged affinity moiety that is attracted to negatively charged nucleic acid molecules. Specific examples of affinity moieties that function via a pH shift are described in Section 2 below.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at col. 28:34-38 (“Step S420 recites heating the set of magnetic bead-sample mixtures to produce a set of nucleic acid-magnetic bead samples, and functions to incubate the set of magnetic bead-sample mixtures in order to lyse biological matter, and release nucleic acids to be bound to magnetic beads.”) <p>US9441219 (Exhibit 53)</p> <ul style="list-style-type: none"> Claim 7: The molecular diagnostic module of claim 1, further comprising: a capture plate comprising a well containing a set of magnetic beads, a lysing reagent, and a sample process control, configured to be combined with the biological sample, wherein the capture plate facilitates production of a magnetic bead-sample from the biological sample and the set of magnetic beads; an assay strip comprising a reagent well containing a molecular diagnostic reagent volume configured to be combined with the nucleic acid volume processed from the magnetic-bead sample, thereby generating a nucleic acid-reagent mixture; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the cartridge, transfer the nucleic acid volume from the cartridge to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip back to the cartridge. Claim 14. The system of claim 8, further comprising a capture plate comprising a well containing a set of magnetic beads, a lysing reagent, and a sample process control, configured to be combined with the biological sample, wherein the capture plate facilitates production of a magnetic bead-sample from the biological sample and the set of magnetic beads; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the cartridge, and configured to transfer a nucleic acid volume processed from the magnetic bead-sample from the cartridge. U.S. Patent No. 9,441,219 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve

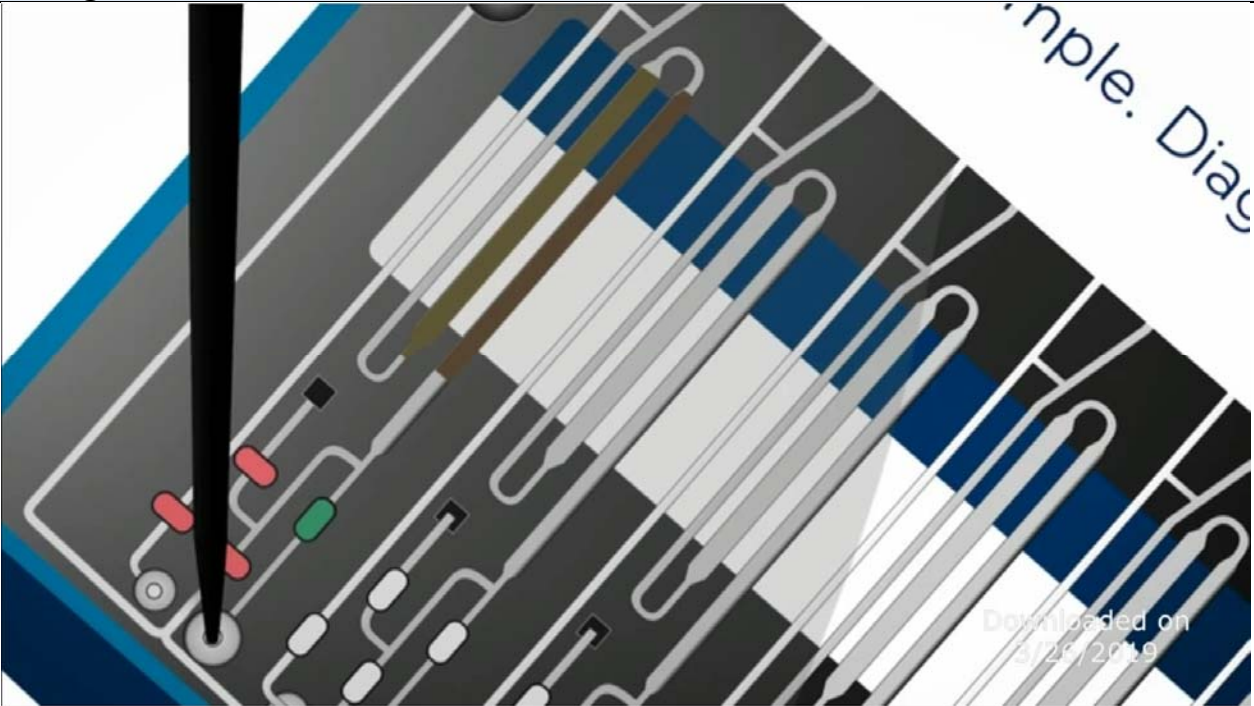
Claim	Claim Language	Infringement Evidence
		<p>actuation Subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical Subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,441,219 at col. 4:23-33 (“The set of wells 112 of the capture plate substrate 111 function to receive at least one biological sample which contain or are suspected of potentially containing nucleic acids, and to facilitate combination of the biological sample with a set of magnetic beads 119. Preferably, the wells 113 are each configured to accommodate not only a biological sample, but also to facilitate mixing of the biological sample with a set of magnetic beads 119 (e.g., using a pipettor, the liquid handling system 250 or other apparatus), which preferably are preloaded in wells 112, or alternatively may be added by an operator.”) • U.S. Patent No. 9,441,219 at col. 27:42-67 (“An embodiment of a method 400 for processing and detecting nucleic acids from a set of biological samples comprises: combining each biological sample of the set of biological samples with a quantity of magnetic beads to produce a set of magnetic bead-sample mixtures S410; heating the set of magnetic bead-sample mixtures to produce a set of nucleic acid-magnetic bead samples S420; transferring each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways S430; producing a set of nucleic acid volumes from the set of nucleic acid-magnetic bead samples S440; combining each nucleic acid volume of the set of nucleic acid volumes with a molecular diagnostic reagent of a set of molecular diagnostic reagents to produce a set of nucleic acid-reagent mixtures S450; transferring each of the set of nucleic acid-reagent mixtures, through the corresponding fluidic pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers S460; and receiving light from the set of nucleic acid-reagent mixtures S470. The method 400 may further comprise generating a set of data based on light received form the set of nucleic acid-reagent mixtures S480. The method 400 functions to isolate and extract a set of nucleic acid volumes from a biological sample, and to facilitate analysis of the nucleic acid volumes according to at least one molecular diagnostic protocol.”) • U.S. Patent No. 9,441,219 at col. 29:10-19 (“Step S420 recites heating the set of magnetic bead-sample mixtures to produce a set of nucleic acid-magnetic bead samples, and functions to incubate the set of magnetic bead-sample mixtures in order to lyse biological matter, and release nucleic acids to be bound to magnetic beads. Preferably, Step S420 comprises heating a capture plate

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		<p>containing the set of magnetic bead-sample mixtures for a specified amount of time at a specified temperature, and may additionally include cooling the set of magnetic bead-sample mixtures.”)</p> <p>US9604213 (Exhibit 30)</p> <ul style="list-style-type: none"> • Claim 1: A system for processing and detecting nucleic acids in cooperation with a cartridge comprising a heating region defined at a first surface, and a magnet housing region defined at a second surface in thermal communication with the first surface, the system comprising: a capture plate configured to facilitate combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate and separate nucleic acids from the set of magnetic beads, comprising: a cartridge platform configured to receive the cartridge and comprising a magnet receiving slot aligned with the second surface during operation, a heater configured to transmit heat to the heating region at the first surface during operation, and a magnet coupled to a magnet heating element that heats the magnet during operation with the magnet proximal the second surface, the magnet configured to pass through the magnet receiving slot into the magnet housing region during operation, thereby facilitating separation of a nucleic acid volume from the magnetic bead-sample and heating of the magnetic bead-sample in cooperation with the heater. • U.S. Patent No. 9,604,213 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling Subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation Subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical Subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay Strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) • U.S. Patent No. 9,604,213 at col. 3:62-66 (“As shown in FIGS. 3A and 3B, the capture plate 110 comprises a capture plate substrate in comprising a set of wells 112 and a puncturable foil seal 115, and functions to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119.”)

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		<ul style="list-style-type: none"> U.S. Patent No. 9,604,213 at col. 4:23-33 (“The set of wells 112 of the capture plate substrate in function to receive at least one biological sample which contain or are suspected of potentially containing nucleic acids, and to facilitate combination of the biological sample with a set of magnetic beads 119. Preferably, the wells 113 are each configured to accommodate not only a biological sample, but also to facilitate mixing of the biological sample with a set of magnetic beads 119 (e.g., using a pipettor, the liquid handling system 250 or other apparatus), which preferably are preloaded in wells 112, or alternatively may be added by an operator.”) <p>US1001888 (Exhibit 55)</p> <ul style="list-style-type: none"> Claim 14: A method for processing and detecting nucleic acids from a sample with a cartridge including a fluidic pathway passing between a heating region of the cartridge and a magnet housing region of the cartridge, wherein the method comprises: with a liquid handling system, combining the sample with a quantity of magnetic beads to produce a nucleic acid-magnetic bead sample; with the liquid handling system, transferring the nucleic acid-magnetic bead sample to the fluidic pathway of the cartridge; and contemporaneously transmitting heat through the heating region, by way of a heater, and transmitting heat through the magnet housing region, by way of a magnet heating element coupled to a magnet, thereby facilitating capture of nucleic acids of the sample at the fluidic pathway of the cartridge. U.S. Patent 10,010,888 at col. 4:29-39 (“The set of wells 112 of the capture plate substrate 111 function to receive at least one biological sample which contain or are suspected of potentially containing nucleic acids, and to facilitate combination of the biological sample with a set of magnetic beads 119. Preferably, the wells 113 are each configured to accommodate not only a biological sample, but also to facilitate mixing of the biological sample with a set of magnetic beads 119 (e.g., using a pipettor, the liquid handling system 250 or other apparatus), which preferably are preloaded in wells 112, or alternatively may be added by an operator.”) U.S. Patent No. 10,010,88 at col. 6:15-29 (“An embodiment of the system 100 may further comprise a capture plate module 120, as shown in FIG. 4, which functions to receive, support, and heat a capture plate 110. The capture plate module 120 preferably comprises a thermally conducting substrate 121 configured to cradle a capture plate 110, a capture plate heater 123, a capture plate receiving module 125, and a capture plate electronics module 127. Preferably, the capture plate module 120 functions to facilitate lysis of a biological sample deposited into a well 113 of the capture plate, and to facilitate binding of nucleic acids (i.e., within a lysed biological sample) to a quantity of magnetic

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		<p>beads 119 within a well 113 of the capture plate 110. In a specific example, the capture plate module 120 has dimensions of 108 mmx156 mmx45 mm and is configured to rest on a flat surface.”)</p>
1(j)	<p>transferring the lysate solution containing the plurality of magnetic binding particles into a first processing region, wherein the first processing region is within a microfluidic network in the system,</p>	<p>The accused workflow comprises transferring the lysate solution containing the plurality of magnetic binding particles into a first processing region, wherein the first processing region is within a microfluidic network in the system.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “After thoroughly mixing the solution in each well of the extraction plate, the crude lysate is independently aspirated from each well and transferred to the NeuMoDx cartridge.” <i>Id.</i> at 1:35-1:51. • 1:51 “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” • 1:56 Microfluidic cartridge  <ul style="list-style-type: none"> • “The liquid handling robot employs total aspiration and dispense monitoring pressure sensing to ensure

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		<p>each tip is securely seated into one of the 12 independent sample ports or s-ports of the cartridge. Once the pipette tip is secured, the entire volume of solution will be dispensed.” <i>Id.</i> at 2:02.</p> <ul style="list-style-type: none"> • 2:07 Dispensing into the s-ports  <ul style="list-style-type: none"> • “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” <i>Id.</i> at 2:24. • 2:28 Lysate in the S-channel (extraction)

Claim	Claim Language	Infringement Evidence
		 <p data-bbox="604 971 1934 1003">40600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 20)</p> <ul data-bbox="653 1011 2011 1154" style="list-style-type: none"> • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p data-bbox="604 1195 1472 1227">40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul data-bbox="653 1235 2011 1378" style="list-style-type: none"> • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound nucleic acid is eluted using the NeuMoDx™ RELEASE Solution.

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		<p>40600106_Rev-D-IFU-NeuMoDx-Lysis-Buffer-1-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 63)</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600105_Rev-D-IFU-NeuMoDx-Lysis-Buffer-2-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 64)</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600104_Rev-D-IFU-NeuMoDx-Lysis-Buffer-3-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 65)</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600103_Rev-D-IFU-NeuMoDx-Lysis-Buffer-4-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 66)</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600100_Rev-D-IFU-NeuMoDx-WASH-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 58)</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40500098_D-IFU-NeuMoDx-Extraction-Plate-US-ONLY (Exhibit 59)</p> <ul style="list-style-type: none"> “The released nucleic acids are captured by magnetic affinity microspheres and these microspheres

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		<p>(along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution.” <i>Id.</i> at 1.</p> <p>US10010888 (Exhibit 55)</p> <ul style="list-style-type: none"> • Claim 16. The method of claim 14, wherein transferring the nucleic acid-magnetic bead sample in to the fluidic pathway of the cartridge comprises transferring the nucleic acid-magnetic bead sample into an s-shaped capture segment passing between the heating region and the magnet housing region of the cartridge. • U.S. Patent No. 10,010,888 at col. 30:45-64 (“An embodiment of a method 400 for processing and detecting nucleic acids from a set of biological samples comprises: combining each biological sample of the set of biological samples with a quantity of magnetic beads to produce a set of magnetic bead-sample mixtures S410; heating the set of magnetic bead-sample mixtures to produce a set of magnetic bead-samples S420; transferring a set of nucleic acid-magnetic bead samples S420; transferring each nucleic acid-magnetic bead sample of the set of nucleic-acid magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways S430; producing a set of nucleic acid volumes from the set of nucleic acid-magnetic bead samples S440; combining each nucleic acid volume of the set of nucleic acid volumes with a molecular diagnostic reagent of a set of molecular diagnostic reagents to produce a set of nucleic acid-reagent mixtures, through the corresponding fluidic pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers S460; and receiving light from the set of nucleic acid-reagent mixtures S470.”) • U.S. Patent No. 10,010,888 at col. 33:12-17 (“Step S430 recites transferring each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways, and functions to isolate each of the set of nucleic acid-magnetic bead samples within separate pathways for further processing.”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 2. The system of claim 1, further comprising a liquid handling system configured to transfer at least one magnetic bead-sample from the capture plate to the molecular diagnostic module, and to aspirate at least one nucleic acid volume from the molecular diagnostic module. • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive

Claim	Claim Language	Infringement Evidence
		<p>and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprising a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer.</p> <ul style="list-style-type: none"> • Claim 24. The system of claim 23, further comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample, a lysing reagent, and a sample process control, wherein the capture plate facilitates production of at least one biological sample combined with magnetic beads; an assay strip comprising at least one reagent well containing molecular diagnostic reagent volume configured to be combined with a nucleic acid volume of the set of nucleic acid volumes to produce at least one nucleic acid-reagent mixture; and a liquid handling system configured to transfer at least one biological sample combined with magnetic beads from the capture plate to the molecular diagnostic module, transfer at least one nucleic acid-reagent mixture from the assay strip back to the molecular diagnostic module. • U.S. Patent No. 9,050,594 at col. 2:49-58 (“As shown in FIGS. 1A-1B and 7A, an embodiment of a system 100 for processing and detecting nucleic acids comprises: a capture plate 110 configured to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119; a molecular diagnostic module 130 comprising a microfluidic cartridge receiving the module 140, heating and cooling subsystems 150, a magnet 160, a valve actuation sub-system 170, an optical subsystem 180; and an assay strip configured to facilitate mixing of molecular diagnostic reagents with a nucleic acid volume.”) • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular

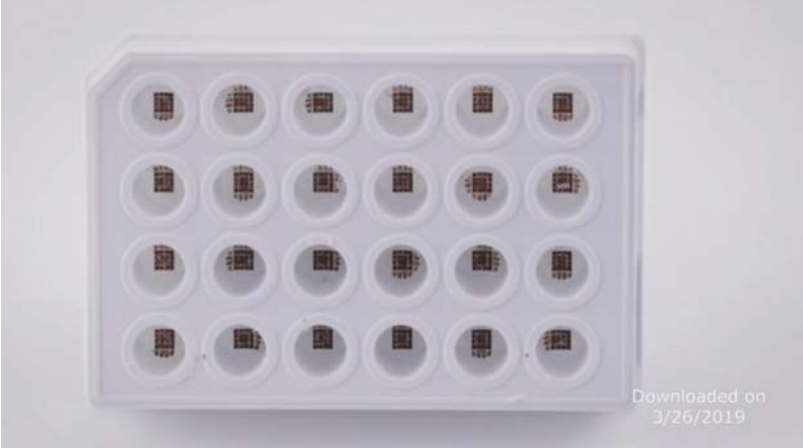

Claim	Claim Language	Infringement Evidence
		<p>diagnostic reagents for analysis of nucleic acids.”)</p> <ul style="list-style-type: none"> <p>U.S. Patent No. 9,050,594 at col. 3:14-46 (“In one example workflow of the system 100, a liquid handling system 250 aspirates a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), and dispenses the set of biological samples into a capture plate 110 to be lysed and combined with magnetic beads (containing a proprietary affinity coating to bind the nucleic acids to the magnetic beads) by a capture plate module 120. The liquid handling system 250 then aspirates substantially all of each sample of the set of lysed biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate no, and dispenses the set of magnetic bead-samples into a microfluidic cartridge 210, aligned within a cartridge receiving module 140 of a molecular diagnostic module 130, and configured to be manipulated by the molecular diagnostic module 130. A heating and cooling subsystem 150, a magnet 160, and a valve actuation subsystem 170 of the molecular diagnostic module 130 then facilitate separation of a set of nucleic acids from the magnetic bead-samples, as the liquid handling system 250 dispenses wash solutions, release solutions, and/or air at appropriate stages. The liquid handling system 250 then aspirates the set of nucleic acids from the microfluidic cartridge 210 contained within the molecular diagnostic module 130, combines the set of nucleic acids with a set of molecular diagnostic reagents using an assay strip 190, and dispenses the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the microfluidic cartridge 210 within the molecular diagnostic module 130. The detection chamber heaters 157, optical subsystem 180 and valve actuation sub-system 170 of the molecular diagnostic module 130 then facilitate analysis of the set of nucleic acid-reagent mixtures by a processor configured to display information on a user interface.”)</p> <p>U.S. Patent No. 9,050,594 at col. 23:32-41 (“As described in Section 1, an embodiment of the liquid handling system 250 is configured to aspirate a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), dispense the set of biological samples into a capture 35 plate no to be lysed and combined with magnetic beads by a capture plate module 120, aspirate the set of biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate 110, and dispense the set of magnetic bead-samples into microfluidic cartridge 210 40 located in a molecular diagnostic module 130.”)</p> <p>U.S. Patent no. 9,050,594 at col 28:53-58 (“Step S430 recites transferring each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic path-ways, and functions to isolate each of the set of nucleic acid-magnetic bead samples</p>

Claim	Claim Language	Infringement Evidence
		<p>within separate pathways for further processing.”)</p> <p>US9441219 (Exhibit 53)</p> <ul style="list-style-type: none"> • Claim 7: The molecular diagnostic module of claim 1, further comprising: a capture plate comprising a well containing a set of magnetic beads, a lysing reagent, and a sample process control, configured to be combined with the biological sample, wherein the capture plate facilitates production of a magnetic bead-sample from the biological sample and the set of magnetic beads; an assay strip comprising a reagent well containing a molecular diagnostic reagent volume configured to be combined with the nucleic acid volume processed from the magnetic-bead sample, thereby generating a nucleic acid-reagent mixture; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the cartridge, transfer the nucleic acid volume from the cartridge to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip back to the cartridge. • Claim 14. The system of claim 8, further comprising a capture plate comprising a well containing a set of magnetic beads, a lysing reagent, and a sample process control, configured to be combined with the biological sample, wherein the capture plate facilitates production of a magnetic bead-sample from the biological sample and the set of magnetic beads; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the cartridge, and configured to transfer a nucleic acid volume processed from the magnetic bead-sample from the cartridge. • U.S. Patent No. 9,441,219 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids. • U.S. Patent No. 9,441,219 at col. 3:28-35 (“The liquid handling system 250 then aspirates substantially all of each sample of the set of lysed biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate no, and dispenses the set of

Claim	Claim Language	Infringement Evidence
		<p>magnetic bead-samples into a microfluidic cartridge 210, aligned within a cartridge receiving module 140 of a molecular diagnostic module 130, and configured to be manipulated by the molecular diagnostic module 130.”</p> <ul style="list-style-type: none"> U.S. Patent No. 9,441,219 at col. 29:30-35 (“Step S430 recites transferring each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways, and functions to isolate each of the set of nucleic acid-magnetic bead samples within separate pathways for further processing.”) <p>US9540636 (Exhibit 54)</p> <ul style="list-style-type: none"> Claim 5. The method of claim 4, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety sample mixture from the process chamber, occluding the fluidic pathway of the cartridge at a set of occlusion positions upon displacement of pins of the set of pins to generate a path through a magnetic field, and to a waste chamber, and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber. Claim 7. The method of claim 3, wherein washing the set of moiety-bound nucleic acid particles comprises aspirating the moiety-sample mixture; receiving the cartridge at the cartridge receiving module comprising the set of pins and a cam card interfacing with the set of pins; transitioning the cartridge to an active configuration that disposes the cartridge to a position that is proximal to the set of pins; displacing the first subset of the set of pins in the active configuration of the cartridge, upon translation of the cam card relative to the set of pins, thereby occluding the fluidic pathway of the cartridge at a set of occlusion positions; delivering the moiety-sample mixture into the fluidic pathway, wherein the fluidic pathway is configured to pass through a magnetic field and is coupled to a waste chamber, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field; and delivering a wash solution through the fluidic pathway and into the waste chamber in a continuous flow operation. Claim 10. The method of claim 3, further comprising releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles, wherein releasing the nucleic acid sample comprises: occluding the fluidic pathway of the cartridge, comprising the process chamber, at a set of occlusion positions, upon displacement of pins of the set of pins, to define a path through a magnetic field; delivering the set of moiety-bound nucleic acid particles into the path of the fluidic pathway; and delivering an

Claim	Claim Language	Infringement Evidence
		<p>elution solution into the fluidic pathway, thereby inducing a pH shift configured to release the nucleic acid sample from the set of moiety-bound nucleic acid particles.</p> <ul style="list-style-type: none"> U.S. Patent No. 9,540,636 at col. 7:52-63 (“In the second variation, the microparticles with bound nucleic acids are retained in a filter zone or a magnetic field zone of the vessel, and the liquid portion is flowed into a “waste chamber. In a specific example of the second variation, a system (such as the one described in U.S. patent application Ser. No. 13/766, 359, entitled “System and Method for Processing and Detecting Nucleic Acids) can be used to transfer the lysed moiety-sample solution into a fluidic pathway of a cartridge (such as the one described in U.S. patent application Ser. No. 13/765,996, entitled “Microfluidic Cartridge for Processing and Detecting Nucleic Acids).”) <p>US9604213 (Exhibit 30)</p> <ul style="list-style-type: none"> Claim 1. A system for processing and detecting nucleic acids in cooperation with a cartridge comprising a heating region defined at a first surface, and a magnet housing region defined at a second surface in thermal communication with the first surface, the system comprising: a capture plate configured to facilitate combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate and separate nucleic acids from the set of magnetic beads, comprising: a cartridge platform configured to receive the cartridge and comprising a magnet receiving slot aligned with the second Surface during operation, a heater configured to transmit heat to the heating region at the first Surface during operation, and a magnet coupled to a magnet heating element that heats the magnet during operation with the magnet proximal the second Surface, the magnet configured to pass through the magnet receiving slot into the magnet housing region during operation, thereby facilitating separation of a nucleic acid Volume from the magnetic bead-sample and heating of the magnetic bead-sample in cooperation with the heater Claim 8. The system of claim 1, further comprising a liquid handling system configured to transfer the magnetic bead sample from the capture plate to the molecular diagnostic module, and to aspirate the nucleic acid volume from the molecular diagnostic module. U.S. Patent No. 9,604,213 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a

Claim	Claim Language	Infringement Evidence
		<p>heating/cooling Subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation Subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical Subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay Strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,604,213 at col. 3:28-35 (“The liquid handling system 250 then aspirates substantially all of each sample of the set of lysed biological samples combined with magnetic beads (i.e., set of magnetic bead samples) from the capture plate no, and dispenses the set of magnetic bead-samples into a microfluidic cartridge 210, aligned within a cartridge receiving module 140 of a molecular diagnostic module 130, and configured to be manipulated by the molecular diagnostic module 130.”)
1(k)	and wherein the lysing container is located external to the microfluidic network	<p>The accused workflow comprises transferring the lysate solution containing the plurality of magnetic binding particles into a first processing region, wherein the first processing region is within a microfluidic network in the system, and wherein the lysing container is located external to the microfluidic network.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936 (Exhibit 16)</p> <ul style="list-style-type: none"> “Liquid Handling Processing A: Lysis and Capture. Dispensing lysis buffer. Dispensing lysis buffer and patient specimen into extraction plate. The liquid handling robot delivers lysis buffer and patient specimen to the extraction plate, which has 24 independent wells which contain NeuDry affinity-coated paramagnetic beads. Each mixture is aspirated and dispensed five times to ensure homogeneity of the solution. During the transfer of patient specimen to the extraction plate the liquid handling robot uses pre-defined no-fly zones to reduce the potential of contamination.” <i>Id.</i> at 0:28-1:05

Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none"> • “Each extraction plate well is then heated independently for 10 minutes to ensure proper lysing and binding of the nucleic acids to the paramagnetic beads. The temperatures applied range from 37 degrees Celsius to 60 degrees Celsius, resulting in the flexibility to process a wide variety of DNA and RNA IVD and LDT tests simultaneously.” <i>Id.</i> at 1:05-1:35 • <i>Id.</i> at 1:16 (showing binding of nucleic acids to paramagnetic beads).  <ul style="list-style-type: none"> • “After thoroughly mixing the solution in each well of the extraction plate, the crude lysate is

Claim	Claim Language	Infringement Evidence
		<p>independently aspirated from each well and transferred to the NeuMoDx cartridge.” <i>Id.</i> at 1:35-1:51.</p> <p>40600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 20)</p> <ul style="list-style-type: none"> • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40500098_D-IFU-NeuMoDx-Extraction-Plate-US-ONLY (Exhibit 59)</p> <ul style="list-style-type: none"> • “The NeuMoDx™ Extraction Plate contains a proprietary, dried reagent used for the efficient extraction of nucleic acids on the NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems (NeuMoDx™ System(s)) in conjunction with other NeuMoDx™ reagents such as NeuMoDx™ lysis buffers, NeuMoDx™ WASH Solution and the NeuMoDx™ RELEASE Solution. The NeuMoDx™ Extraction Plate is universally used for all tests processed on the NeuMoDx Systems and is formulated to perform both RNA and DNA extraction.” <i>Id.</i> at 1. • “Each 24-well NeuMoDx Extraction Plate contains dried, room-temperature stable reagents including proprietary coated magnetic microspheres, a lytic enzyme, and RNA and DNA Sample Process Controls. Components within the extraction plate work in conjunction with the appropriate NeuMoDx lysis buffer to lyse cells in a temperature dependent manner and bind the nucleic acid while reducing activity of any nucleases present in clinical samples. The Sample Process Controls bind to the magnetic microspheres at the same time as the target nucleic acid, and are carried throughout the extraction procedure, serving as internal controls to monitor for any inefficiencies in the extraction process and presence of PCR interference substances.” <i>Id.</i> at 1. • “The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate lysis buffer in the NeuMoDx Extraction Plate and is subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres.” <i>Id.</i> at 1. • “The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the

Claim	Claim Language	Infringement Evidence																								
		<p>unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution.” <i>Id.</i> at 1.</p> <p><i>Material Provided</i></p> <table><tr><th>REF</th><th>Contents</th><th>Tests per unit</th><th>Tests per carton</th></tr><tr><td>100200</td><td>NeuMoDx™ Extraction Plate <i>Dried magnetic affinity microspheres, lytic enzymes, and sample process controls</i></td><td>24</td><td>384</td></tr></table> <p><i>NeuMoDx™ Reagents and Consumables Required But Not Provided</i></p> <table><tr><th>REF</th><th>Contents</th></tr><tr><td>400400, 400500 400600, 400700</td><td>NeuMoDx™ Lysis Buffer 1, 2, 3 and/or 4</td></tr><tr><td>400100</td><td>NeuMoDx™ WASH Solution</td></tr><tr><td>400200</td><td>NeuMoDx™ RELEASE Solution</td></tr><tr><td>100100</td><td>NeuMoDx™ Cartridge</td></tr><tr><td><i>various</i></td><td>NeuMoDx™ test strip (<i>as applicable</i>)</td></tr><tr><td>235903</td><td>Hamilton CO-RE Tips (300 µL) with Filters (available from NeuMoDx or Hamilton)</td></tr><tr><td>235905</td><td>Hamilton CO-RE Tips (1000 µL) with Filters (available from NeuMoDx or Hamilton)</td></tr></table> <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none">• The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx™ lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres.• The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound nucleic acid is eluted using the NeuMoDx™ RELEASE Solution.	REF	Contents	Tests per unit	Tests per carton	100200	NeuMoDx™ Extraction Plate <i>Dried magnetic affinity microspheres, lytic enzymes, and sample process controls</i>	24	384	REF	Contents	400400, 400500 400600, 400700	NeuMoDx™ Lysis Buffer 1, 2, 3 and/or 4	400100	NeuMoDx™ WASH Solution	400200	NeuMoDx™ RELEASE Solution	100100	NeuMoDx™ Cartridge	<i>various</i>	NeuMoDx™ test strip (<i>as applicable</i>)	235903	Hamilton CO-RE Tips (300 µL) with Filters (available from NeuMoDx or Hamilton)	235905	Hamilton CO-RE Tips (1000 µL) with Filters (available from NeuMoDx or Hamilton)
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		<p>heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at col. 2:49-58 (“As shown in FIGS. 1A-1B and 7A, an embodiment of a system 100 for processing and detecting nucleic acids comprises: a capture plate 110 configured to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119; a molecular diagnostic module 130 comprising a microfluidic cartridge receiving the module 140, heating and cooling subsystems 150, a magnet 160, a valve actuation sub-system 170, an optical subsystem 180; and an assay strip configured to facilitate mixing of molecular diagnostic reagents with a nucleic acid volume.”) U.S. Patent No. 9,050,594 at col. 3:14-28 (“In one example workflow of the system 100, a liquid handling system 250 aspirates a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), and dispenses the set of biological samples into a capture plate 110 to be lysed and combined with magnetic beads (containing a proprietary affinity coating to bind the nucleic acids to the magnetic beads) by a capture plate module 120. The liquid handling system 250 then aspirates substantially all of each sample of the set of lysed biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate no, and dispenses the set of magnetic bead-samples into a microfluidic cartridge 210, aligned within a cartridge receiving module 140 of a molecular diagnostic module 130, and configured to be manipulated by the molecular diagnostic module 130.”) <p>US9441219 (Exhibit 53)</p> <ul style="list-style-type: none"> Claim 7. The molecular diagnostic module of claim 1, further comprising: a capture plate comprising a well containing a set of magnetic beads, a lysing reagent, and a sample process control, configured to be combined with the biological sample, wherein the capture plate facilitates production of a magnetic bead-sample from the biological sample and the set of magnetic beads; an assay strip comprising a reagent well containing a molecular diagnostic reagent volume configured to be combined with the nucleic acid volume processed from the magnetic-bead sample, thereby generating a nucleic acid-reagent mixture; and a liquid handling system configured to transfer the magnetic bead-sample

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		<p>from the capture plate to the cartridge, transfer the nucleic acid volume from the cartridge to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip back to the cartridge.</p> <ul style="list-style-type: none"> • Claim 14. The system of claim 8, further comprising a capture plate comprising a well containing a set of magnetic beads, a lysing reagent, and a sample process control, configured to be combined with the biological sample, wherein the capture plate facilitates production of a magnetic bead-sample from the biological sample and the set of magnetic beads; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the cartridge, and configured to transfer a nucleic acid volume processed from the magnetic bead-sample from the cartridge. • U.S. Patent No. 9,441,219 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids. <p>US9604213 (Exhibit 30)</p> <ul style="list-style-type: none"> • Claim 1. A system for processing and detecting nucleic acids in cooperation with a cartridge comprising a heating region defined at a first Surface, and a magnet housing region defined at a second surface in thermal communication with the first surface, the system comprising: a capture plate configured to facilitate combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate and separate nucleic acids from the set of magnetic beads, comprising: a cartridge platform configured to receive the cartridge and comprising a magnet receiving slot aligned with the second Surface during operation, a heater configured to transmit heat to the heating region at the first Surface during operation, and a magnet coupled to a magnet heating element that heats the magnet during operation with the magnet proximal the second surface, the magnet configured to pass through the magnet receiving slot into the magnet housing region during

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		<p>operation, thereby facilitating separation of a nucleic acid volume from the magnetic bead-sample and heating of the magnetic bead-sample in cooperation with the heater.</p> <ul style="list-style-type: none"> • Claim 8. The system of claim 1, further comprising a liquid handling system configured to transfer the magnetic bead sample from the capture plate to the molecular diagnostic module, and to aspirate the nucleic acid volume from the molecular diagnostic module. • U.S. Patent No. 9,604,213 col. 3:62-66 (“As shown in FIGS. 3A and 3B, the capture plate 110 comprises a capture plate substrate in comprising a set of wells 112 and a puncturable foil seal 115, and functions to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119.”) <p>US9339812 (Exhibit 26)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,339,812 at 2:49-58 (“As shown in FIGS. 1A-1B and 7A, an embodiment of a system 100 for processing and detecting nucleic acids comprises: a capture plate 110 configured to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119; a molecular diagnostic module 130 comprising a microfluidic cartridge receiving module 140, heating and cooling subsystem 150, a magnet 160, a valve actuation sub-system 170, an optical subsystem 180; and an assay strip 190 configured to facilitate mixing of molecular diagnostic reagents with a nucleic acid volume. • U.S. Patent No. 9,339,812 at col. 3:14-28 (“In one example workflow of the system 100, a liquid handling system 250 aspirates a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), and dispenses the set of biological samples into a capture plate 110 to be lysed and combined with magnetic beads (containing a proprietary affinity coating to bind the nucleic acids to the magnetic beads) by a capture plate module 120. The liquid handling system 250 then aspirates substantially all of each sample of the set of lysed biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate no, and dispenses the set of magnetic bead-samples into a microfluidic cartridge 210, aligned within a cartridge receiving module 140 of a molecular diagnostic module 130, and configured to be manipulated by the molecular diagnostic module 130.”)
1(l)	capturing the plurality of magnetic binding particles	The accused workflow comprises capturing the plurality of magnetic binding particles in the first processing region.

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	in the first processing region,	<p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMoDx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” <i>Id.</i> at 2:24-2:28. <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> • Claim 6. The method of claim 5, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety-sample mixture from the process chamber; occluding the fluidic pathway of the cartridge-at a set of occlusion positions upon displacement of pins of the set of pins to generate a path through a magnetic field, and to a waste chamber; and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber. • Claim 10. The method of claim 3, wherein washing the set of moiety-bound nucleic acid particles comprises aspirating the moiety-sample mixture; receiving the cartridge at the cartridge receiving module comprising the set of pins and a cam card interfacing with the set of pins; transitioning the cartridge to an active configuration that disposes the cartridge proximal the set of pins; displacing the first subset of the set of pins in the active configuration of the cartridge, upon translation of the cam card relative to the set of pins, thereby occluding the fluidic pathway of the cartridge at a set of occlusion positions; delivering the moiety-sample mixture into the fluidic pathway, wherein the fluidic pathway is configured to pass through a magnetic field and is coupled to a waste chamber, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field; and delivering a wash solution through the fluidic pathway and into the waste chamber in a continuous flow operation.. • Claim 14. The method of claim 13, further comprising capturing the set of moiety-bound nucleic acid particles within the magnetic field and aspirating the nucleic acid sample from the fluidic pathway. • Claim 18. The method of claim 17, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety-sample mixture from the process chamber; occluding the fluidic pathway of the cartridge at a set of occlusion

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		<p>positions upon displacement of the first subset of the set of pins to generate a path through a magnetic field, and to a waste chamber of the cartridge; and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber.</p> <ul style="list-style-type: none"> U.S. Patent No. 9,382,532 at 7:31-54 “In a second variation, the lysed moiety-sample solution can be transferred to a vessel that enables the moiety-bound nucleic acid volume to be captured and the waste volume to be removed in a flow through manner, either against the pores of a filter or in the presence of a magnetic field. In the second variation, the microparticles with bound nucleic acids are retained in a filter zone or a magnetic field zone of the vessel, and the liquid portion is flowed into a "waste chamber". In a specific example of the second variation, a system (such as the one described in U.S. patent application Ser. No. 13/766,359, entitled "System and Method for Processing and Detecting Nucleic Acids") can be used to transfer the lysed moiety-sample solution into a fluidic pathway of a cartridge (such as the one described in U.S. patent application Ser. No. 13/765,996, entitled "Microfluidic Cartridge for Processing and Detecting Nucleic Acids"). In the specific example, the lysed moiety-sample solution can be retained by a magnetic field within a portion of the fluidic pathway upon occlusion of the fluidic pathway at a suitable set of occlusion positions, in order to separate the moiety-bound nucleic acid volume from the waste volume. The waste volume can then be removed by pushing the waste volume to a waste chamber of the cartridge.”) Patent No. 9,382,532 at 24:57-25:2 (“For example, as shown in FIG. 22B, occluding the fluidic pathway 165 at the first, third, fourth, and sixth occlusion positions 142, 144, 145, 147 forms a truncated pathway by which a volume of a sample fluid, comprising nucleic acids bound to magnetic beads and delivered into the sample port 114, may flow past the second occlusion positions 143 into the capture segment 166 for isolation and purification of nucleic acids using the heating region 195 and the magnetic field 156. Nucleic acids bound to magnetic beads may thus be trapped within the capture segment 166 by the magnetic field 156, while other substances in the volume of sample fluid may pass into the waste chamber 130 by passing the fifth occlusion position 146..”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to

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		<p>process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • Claim 8. The system of claim 1, wherein the magnet is configured to provide a magnetic field spanning at least three fluidic pathways configured to facilitate isolation and extraction of three nucleic acid volumes. • U.S. Patent no. 9,050,094 at col. 29:35-40 (“Step S440 preferably includes providing a magnetic field S441, such that each fluidic pathway in the set of fluidic pathways is configured to cross the magnetic field. Preferably, the set of nucleic acid-magnetic bead samples is captured and isolated within portions of the set of fluidic pathways crossing the magnetic field.”) • U.S. Patent no. 9,050,094 at col. 30:15-20 (“The liquid handling system delivers a wash fluid through the shared fluid port to wash the set of nucleic acid-magnetic bead samples, captured within the magnetic field, and then delivers a release fluid through the shared fluid port to release a set of nucleic acid volumes from the set of nucleic acid-magnetic bead samples.”) <p>US9452430 (Exhibit 56)</p> <ul style="list-style-type: none"> • Claim 9. The cartridge of claim 1, wherein the sealed waste chamber further defines a second external void parallel to the external void and configured to receive a magnet, wherein the second external void provides access to a magnetic capture segment of the fluidic pathway, wherein the magnetic capture segment is downstream of the sample port and upstream of the waste port. • Claim 10. The cartridge of claim 9, wherein the intermediate substrate includes a magnet proximal the second external void and the magnetic capture segment. • Claim 13. The cartridge of claim 12, wherein the first fluidic pathway comprises a capture segment, wherein the capture segment is s-shaped and progressively narrowing in an upstream-to-downstream direction • U.S. Patent No. 9,452,430 at col. 12:55-58 (“The magnet housing region 150 of the microfluidic

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		<p>cartridge 100 functions to provide access to and/or house at least one magnet 152 providing a magnetic field 156 for purification and isolation of nucleic acids.")</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,452,430 at col. 16:31-43 ("The occlusion positions of the set of occlusion positions 141 of the first embodiment are preferably located such that occluding subsets of the set of occlusion positions 141 defines unique truncated fluidic pathways to controllably direct fluid flow. For example, as shown in FIG. 1D, occluding the fluidic pathway 165 at the first, third, fourth, and sixth occlusion positions 142, 144, 145, 147 forms a truncated pathway y which a volume of a sample fluid, comprising nucleic acids bound to magnetic beads and delivered into the sample port 114, may flow past the second occlusion position 143 into the capture segment 166 for isolation and purification of nucleic acids using the heating region 195 and the magnetic field 156. Nucleic acids bound to magnetic beads may thus be trapped within the capture segment 166 by the magnetic field 156, while other substances in the volume of sample fluid may pass into the waste chamber 130 by passing the fifth occlusion position 146.") • U.S. Patent No. 9,452,430 at col. 19:13-17 ("Nucleic acids bound to magnetic beads may thus be trapped within the capture segment 166' by the magnetic field 156, while other substances in the volume of sample fluid may pass into the waste chamber 130 by passing the fifth occlusion position 146".) • U.S. Patent No. 9,452,430 at col. 25:16-21 ("Furthermore, the S-shaped capture segment 166 of a fluidic pathway of the specific embodiment is configured to have a volume capacity of 22 uL, have a width of 5.5 mm, and weave back and forth over a magnetic field 156, by crossing the magnet housing region 150.") <p>US9540636 (Exhibit 54)</p> <ul style="list-style-type: none"> • Claim 7. The method of claim 3, wherein washing the set of moiety-bound nucleic acid particles comprises aspirating the moiety-sample mixture; receiving the cartridge at the cartridge receiving module comprising the set of pins and a cam card interfacing with the set of pins; transitioning the cartridge to an active configuration that disposes the cartridge to a position that is proximal to the set of pins; displacing the first subset of the set of pins in the active configuration of the cartridge, upon translation of the cam card relative to the set of pins, thereby occluding the fluidic pathway of the cartridge at a set of occlusion positions; delivering the moiety-sample mixture into the fluidic pathway, wherein the fluidic pathway is configured to pass through a magnetic field and is coupled to a waste chamber, such that the set of moiety-bound nucleic acid particles is captured within the magnetic

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		<p>field; and delivering a wash solution through the fluidic pathway and into the waste chamber in a continuous flow operation.</p> <ul style="list-style-type: none"> U.S. Patent No. 9,540,636 at col. 25:52-60 (“A first illustration of the eighteenth example, as shown in FIG.22A, of a fluidic pathway 165 preferably comprises an initial segment 174 fluidically coupled to a fluid channel 119 coupled to a shared fluid port 118, a sample segment 175 coupled to a sample port 114 and to the initial segment 174, and an S-shaped capture segment 166, configured to pass through the heating region 195 and a magnetic field 156, coupled to the initial segment 174 and the sample segment 175.”) <p>US9604213 (Exhibit 30)</p> <ul style="list-style-type: none"> Claim 4. The system of claim 3, wherein the capture segment is an S-shaped capture segment, and wherein in an operation mode of the system the magnet is configured to cross a subset of the capture segment in a direction perpendicular to a flow direction through the capture segment thereby providing a magnetic field at the subset of the capture segment to capture the magnetic bead-sample within the capture segment. U.S. Patent No. 9,604,213 at col. 15:57-64 (“In any of the above embodiments and variations of the magnet(s), the magnet(s) are preferably configured to span a substantial portion of a capture segment 263 (e.g., an S-shaped capture segment with a characteristic width) of the microfluidic cartridge 210, by way of the magnet housing region 218, therein the capture segment is a portion of a fluidic pathway configured to facilitate capture of target particles bound to magnetic particles.”)
1(m)	wherein excess lysate solution flows through the first processing region into a waste chamber;	<p>The accused workflow comprises capturing the plurality of magnetic binding particles in the first processing region, wherein excess lysate solution flows through the first processing region into a waste chamber.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” <i>Id.</i> at 2:28-2:39. “A precise volume of air is then applied to remove any remaining liquid into the waste chamber. NeuMoDx wash solution is pumped via the fluid port into the microfluidic cartridge to remove all unbound material, followed by another volume of air to remove excess wash solution.” <i>Id.</i> at 2:39-

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		<p>2:43.</p> <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY (Exhibit 19)</p> <ul style="list-style-type: none"> • “Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System. The NeuMoDx Cartridge also incorporates a chamber to contain all the liquid waste generated in the course of processing the samples.” <i>Id.</i> at 1. <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> • Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position of the fluidic pathway, by way of the void of the corrugated surface, the fluidic pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber. • Claim 3. The cartridge of claim 1, wherein the waste chamber comprises at least one waste inlet in communication with the opening of the intermediate substrate, and wherein the corrugated surface of the waste chamber further defines a rectangular prismatic void spanning a long dimension of the cartridge that defines a magnet housing region configured to reversibly receive a magnet from the direction perpendicular to a broad face of the first layer, and configured to cross the fluidic pathway. • Claim 5. The cartridge of claim 4, wherein the fluidic pathway is configured to transfer waste fluid of the sample to the waste chamber through a first waste inlet upstream of the capture segment by way of a first waste segment fluidly coupled to the fluid waste inlet and an initiating portion of the capture segment, and wherein the fluidic pathway is configured to transfer a second waste fluid to the waste chamber through a second waste inlet downstream of the capture segment by way of a second waste segment fluidly coupled to the second waste inlet and a terminating portion of the capture segment.

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		<ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at Abstract (“A microfluidic cartridge, configured to facilitate processing and detection of nucleic acids, comprising: a top layer comprising a set of cartridge-aligning indentations, a set of sample port-reagent port pairs, a shared fluid port, a vent region, a heating region, and a set of detection chambers; an intermediate Substrate, coupled to the top layer comprising a waste chamber, an elastomeric layer, partially situated on the intermediate Substrate; and a set of fluidic pathways, each formed by at least a portion of the top layer and a portion of the elastomeric layer, wherein each fluidic pathway is fluidically coupled to a sample port-reagent port pair, the shared fluid port, and a detection chamber, comprises a turnabout portion passing through the heating region, and is configured to be occluded upon deformation of the elastomeric layer, to transfer a waste fluid to the waste chamber, and to pass through the vent region.”) U.S. Patent No. 9,403,165 at col. 9:57-10:3 (“As shown in FIG. 1B, the intermediate substrate 120 of an embodiment of the microfluidic cartridge 100 is configured to form a waste chamber 130, which functions to receive and isolate waste fluids generated within the microfluidic cartridge 100. The waste chamber 130 is preferably continuous and accessible by each fluidic pathway 165 of the microfluidic cartridge 100, such that all waste fluids generated within the microfluidic cartridge 100 are deposited into a common waste chamber; however, each fluidic pathway 165 of the microfluidic cartridge 100 may alternatively have its own corresponding waste chamber 130, such that waste fluids generated within a fluidic pathway 165 of the microfluidic cartridge 100 are isolated from waste fluids generated within other fluidic pathways 165 of the microfluidic cartridge 100.”) <p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at Abstract (“A microfluidic cartridge, configured to facilitate processing and detection of nucleic acids, comprising: a top layer comprising a set of cartridge-aligning indentations, a set of sample port-reagent port pairs, a shared fluid port, a vent region, a heating region, and a set of detection chambers; an intermediate substrate, coupled to the top layer comprising a waste chamber; an elastomeric layer, partially situated on the intermediate substrate; and a set of fluidic pathways, each formed by at least a portion of the top layer and a portion of the elastomeric layer, wherein each fluidic pathway is fluidically coupled to a sample port-reagent port pair, the shared fluid port, and a Detection chamber, comprises a turnabout portion passing through the heating region, and is configured to be occluded upon deformation of the elastomeric layer, to transfer a waste fluid to the waste chamber, and to pass through the vent region.”) US Patent No. 9,738,887 at 2:36-3:5. (“As shown in FIGS. 1A-1C, an embodiment of a microfluidic

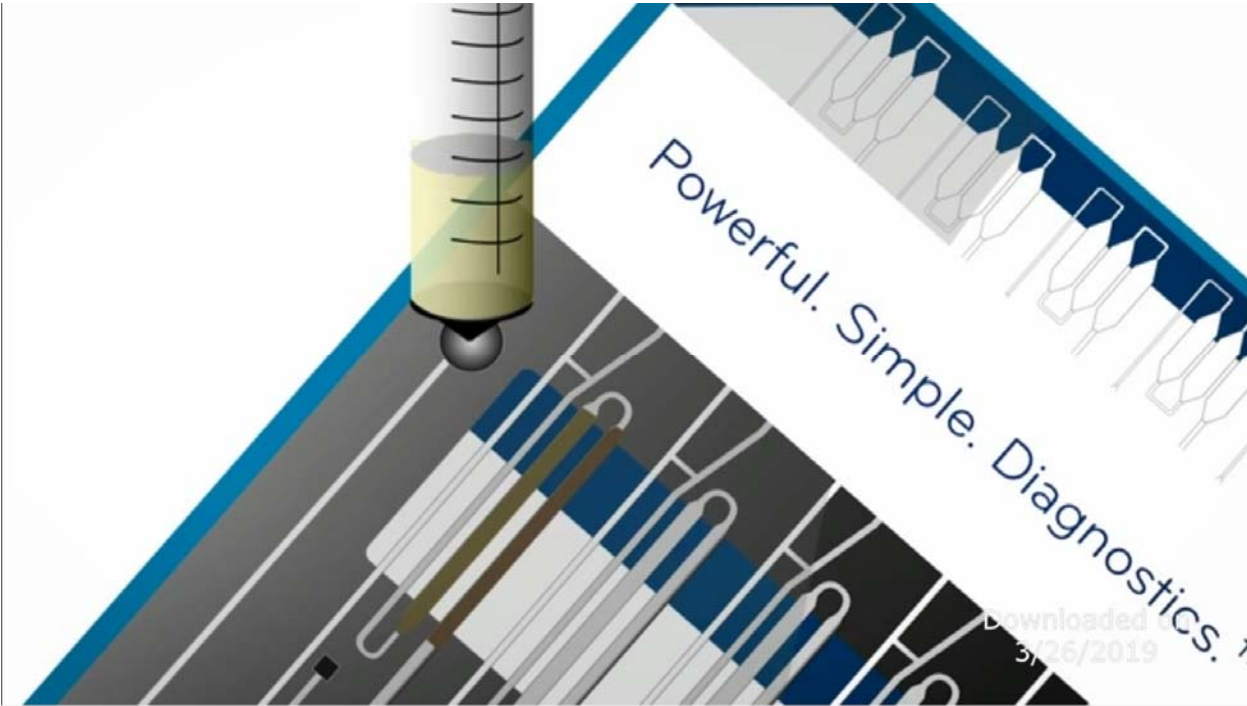
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		<p>cartridge 100 for processing and detecting nucleic acids comprises: a top layer 110 comprising a set of sample port-reagent port pairs 112 and a set of detection chambers 116; an intermediate substrate 120, coupled to the top layer 110 and partially separated from the top layer by a film layer 125, configured to form a waste chamber 130; an elastomeric layer 140 partially situated on the intermediate substrate 120; a magnet housing region 150 accessible by a magnet 152 providing a magnetic field 156; and a set of fluidic pathways 160, each formed by at least a portion of the top layer 110, a portion of the film layer 125, and a portion of the elastomeric layer 140... In a specific application, the microfluidic cartridge 100 can be used to facilitate a PCR procedure for analysis of a sample containing nucleic acids.”)</p> <ul style="list-style-type: none"> US Patent No. 9,738,887 at 13:35-42. (“The set of fluidic pathways 160 of the microfluidic cartridge 100 functions to provide a fluid network into which volumes of sample fluids, reagents, buffers and/or gases used in a molecular diagnostics protocol may be delivered, out of which waste fluids may be eliminated, and by which processed nucleic acid samples may be delivered to a detection chamber for analysis, which may include amplification and/or detection.”) <p>US9101930 (Exhibit 25)</p> <ul style="list-style-type: none"> Claim 10. A cartridge, configured to facilitate processing and detecting of nucleic acids, comprising: a first layer and an intermediate substrate, coupled to the first layer, wherein the intermediate substrate defines a waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids spanning a majority of a width of the intermediate substrate and external to the waste chamber, wherein the set of voids is accessible from a direction perpendicular to a broad surface of the first layer; a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway, formed by at least a portion of the first layer, wherein the first fluidic pathway and the second fluidic pathway are each superior to the intermediate substrate, are each at least partially separated from the corrugated surface of the intermediate substrate by an elastomeric layer and are each configured to transfer waste to the waste chamber through a set of openings of the intermediate substrate. U.S. Patent No. 9,101,930 at Abstract (“A microfluidic cartridge, configured to facilitate processing and detection of nucleic acids, comprising: a top layer comprising a set of cartridge-aligning indentations, a set of sample port-reagent port pairs, a shared fluid port, a vent region, a heating region, and a set of detection chambers; an intermediate substrate, coupled to the top layer comprising a waste chamber, an elastomeric layer, partially situated on the intermediate substrate; and a set of


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		<p>fluidic pathways, each formed by at least a portion of the top layer and a portion of the elastomeric layer, wherein each fluidic pathway is fluidically coupled to a sample port-reagent port pair, the shared fluid port, and a Detection chamber, comprises a turnabout portion passing through the heating region, and is configured to be occluded upon deformation of the elastomeric layer, to transfer a waste fluid to the waste chamber, and to pass through the vent region.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,101,903 at col. 9:54-67 (“As shown in FIG. 1B, the intermediate substrate 120 of an embodiment of the microfluidic cartridge 100 is configured to form a waste chamber 130, which functions to receive and isolate waste fluids generated within the microfluidic cartridge 100. The waste chamber 130 is preferably continuous and accessible by each fluidic pathway 165 of the microfluidic cartridge 100, such that all waste fluids generated within the microfluidic cartridge 100 are deposited into a common waste chamber; however, each fluidic pathway 165 of the microfluidic cartridge 100 may alternatively have its own corresponding waste chamber 130, such that waste fluids generated within a fluidic pathway 165 of the microfluidic cartridge 100 are isolated from waste fluids generated within other fluidic pathways 165 of the microfluidic cartridge 100.”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprising a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. U.S. Patent No. col. 29:57-63 (“Preferably, Step S443 comprises defining at least one truncated fluidic pathway coupled to a waste chamber and to a fluid port, which functions to facilitate washing of at least one nucleic acid-magnetic bead sample in the set of nucleic acid-magnetic bead samples, and releasing of at least one nucleic acid volume from the set of nucleic acid-magnetic bead samples.”) <p>US9452430 (Exhibit 56)</p> <ul style="list-style-type: none"> Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port; an intermediate substrate that is coupled to the first layer, partially separated from the first layer by a film layer, and configured to form a sealed waste chamber and a waste port into the

Claim	Claim Language	Infringement Evidence
		<p>sealed waste chamber, wherein the sealed waste chamber directly opposes the first layer across the film layer and defines an external void; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the sealed waste chamber by a deformably layer, wherein the fluidic pathway is fluidly coupled to the sample port, and wherein, upon deformation of the deformable layer through the external void defined by the waste chamber, the fluidic pathway is occluded and configured to transfer waste fluid of the sample through the waste port into an interior portion of the sealed waste chamber.</p> <ul style="list-style-type: none"> • Claim 11. The cartridge for processing of a set of samples, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate forms a sealed waste chamber and a set of waste ports into the sealed waste chamber, wherein the sealed waste chamber directly opposes the first layer across the film layer and defines an external void; a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the first layer, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the sealed wax chamber by a deformable layer that is deformed through the external void, and each of the first and second fluidic pathways is configured to transfer waste fluid of the set of samples into the sealed waste chamber through the set of waste ports. • Claim 12. The cartridge of claim 11, wherein the deformable layer includes a set of waste openings aligned with the set of waste ports, thereby allowing transfer of waste fluid from the set of samples into the sealed waste chamber. • U.S. Patent No. 9,452,430 at Abstract (“A microfluidic cartridge, configured to facilitate processing and detection of nucleic acids, comprising: a top layer comprising a set of cartridge-aligning indentations, a set of sample port-reagent port pairs, a shared fluid port, a vent region, a heating region, and a set of Detection chambers; an intermediate Substrate, coupled to the top layer comprising a waste chamber; an elastomeric layer, partially situated on the intermediate substrate; and a set of fluidic pathways, each formed by at least a portion of the top layer and a portion of the elastomeric layer, wherein each fluidic pathway is fluidically coupled to a sample port-reagent port pair, the shared fluid port, and a Detection chamber, comprises a turnabout portion passing through the heating region, and is configured to be occluded upon deformation of the elastomeric layer, to transfer a waste fluid to the waste chamber, and to pass through the vent region.”) • U.S. Patent No. 9,452,430 at col. 10:3-17 (“As shown in FIG. 1B, the intermediate substrate 120 of an embodiment of the microfluidic cartridge 100 is configured to form a waste chamber 130, which

Claim	Claim Language	Infringement Evidence
		<p>functions to receive and isolate waste fluids generated within the microfluidic cartridge 100. The waste chamber 130 is preferably continuous and accessible by each fluidic pathway 165 of the microfluidic cartridge 100, such that all waste fluids generated within the microfluidic cartridge 100 are deposited into a common waste chamber; however, each fluidic pathway 165 of the microfluidic cartridge 100 may alternatively have its own corresponding waste chamber 130, such that waste fluids generated within a fluidic pathway 165 of the microfluidic cartridge 100 are isolated from waste fluids generated within other fluidic pathways 165 of the microfluidic cartridge 100.”)</p> <p>US9540636 (Exhibit 54)</p> <ul style="list-style-type: none"> • Claim 5. The method of claim 4, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety sample mixture from the process chamber, occluding the fluidic pathway of the cartridge at a set of occlusion positions upon displacement of pins of the set of pins to generate a path through a magnetic field, and to a waste chamber, and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber. • U.S. Patent No. 9,540,636 at Abstract (“A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber; mixing the binding moiety solution with a biological sample, within the process chamber, in order to produce a moiety-sample mixture; incubating the moiety-sample mixture during a time window, thereby producing a solution comprising a set of moiety-bound nucleic acid particles and a waste volume; separating the set of moiety-bound nucleic acid particles from the waste volume; washing the set of moiety-bound nucleic acid particles; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles. The method preferably utilizes a binding moiety comprising at least one of poly(allylamine) and polypropylenimine tetramine dendrimer, both of which reversibly bind and unbind to nucleic acids based upon environmental pH.”) • U.S. Patent No. 9,540,636 at col. 3:14-25 (“As shown in FIGS. 1A and 2, a method 100 for nucleic acid isolation comprises receiving a binding moiety solution within a process chamber S110; mixing the binding moiety solution with a biological sample, within the process chamber, in order to produce a moiety-sample solution S120; incubating the moiety-sample solution during a time window S130, thereby producing a lysed solution comprising a moiety-bound nucleic acid volume and a waste volume; separating the moiety-bound nucleic acid volume from the waste volume S140; washing

Claim	Claim Language	Infringement Evidence												
		<p>the moiety-bound nucleic acid volume S150; and releasing a nucleic acid sample from the moiety-bound nucleic acid volume S160.”)</p> <ul style="list-style-type: none">U.S. Patent No. 9,540,636 at col. 6:34-37 (“In all of the specific examples and variations, the incubation produces a lysed moiety-sample solution comprising a volume of affinity moiety-bound nucleic acids and a waste volume for removal.”)U.S. Patent No. 7:55-8:3 (“In a specific example of the second variation, a system (such as the one described in U.S. patent application Ser. No. 13/766,359, entitled “System and Method for Processing and Detecting Nucleic Acids) can be used to transfer the lysed moiety-sample solution into a fluidic pathway of a cartridge (such as the one described in U.S. patent application Ser. No. 13/765,996, entitled “Microfluidic Cartridge for Processing and Detecting Nucleic Acids). In the specific example, the lysed moiety-sample solution can be retained by a magnetic field within a portion of the fluidic pathway upon occlusion of the fluidic pathway at a suitable set of occlusion positions, in order to separate the moiety-bound nucleic acid volume from the waste volume. The waste volume can then be removed by pushing the waste volume to a waste chamber of the cartridge.”)												
1(n)	introducing a wash solution into the first processing region to remove unbound material not retained by the plurality of magnetic binding particles;	<p>The accused workflow comprises introducing a wash solution into the first processing region to remove unbound material not retained by the plurality of magnetic binding particles.</p> <p>406001113 Rev-A-SDS-NeuMoDx-Wash-Solution-FINAL.pdf (Exhibit 72)</p> <p><u>General Information</u></p> <table><tr><td>Form:</td><td>Liquid</td></tr><tr><td>Color:</td><td>Clear</td></tr><tr><td>Odor:</td><td>Odorless</td></tr><tr><td>pH Value at 20°C (68°F)</td><td>pH 7.0-8.1</td></tr><tr><td>melting point/melting range:</td><td>Not determined</td></tr><tr><td>Boiling point/boiling range:</td><td>Not determined</td></tr></table> <ul style="list-style-type: none">Received in processing region <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at</p>	Form:	Liquid	Color:	Clear	Odor:	Odorless	pH Value at 20°C (68°F)	pH 7.0-8.1	melting point/melting range:	Not determined	Boiling point/boiling range:	Not determined
Form:	Liquid													
Color:	Clear													
Odor:	Odorless													
pH Value at 20°C (68°F)	pH 7.0-8.1													
melting point/melting range:	Not determined													
Boiling point/boiling range:	Not determined													

Claim	Claim Language	Infringement Evidence
		<p data-bbox="604 235 1318 267">https://player.vimeo.com/video/299307936 (Exhibit 16)</p> <ul data-bbox="653 272 2022 454" style="list-style-type: none"> <li data-bbox="653 272 2022 414">• “A precise volume of air is then applied to remove any remaining liquid into the waste chamber. NeuMoDx wash solution is pumped via the fluid port into the microfluidic cartridge to remove all unbound material, followed by another volume of air to remove excess wash solution.” <i>Id.</i> at 2:39-2:43. <li data-bbox="653 418 947 454">• 2:43 Wash solution  <ul data-bbox="653 1161 1108 1190" style="list-style-type: none"> <li data-bbox="653 1161 1108 1190">• 2:45 Wash solution in s-channel

Claim	Claim Language	Infringement Evidence
		 <p>40600106_Rev-D-IFU-NeuMoDx-Lysis-Buffer-1-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 63)</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600105_Rev-D-IFU-NeuMoDx-Lysis-Buffer-2-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 64)</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution.

Claim	Claim Language	Infringement Evidence
		<p>40600104_Rev-D-IFU-NeuMoDx-Lysis-Buffer-3-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 65)</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600103_Rev-D-IFU-NeuMoDx-Lysis-Buffer-4-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 66)</p> <ul style="list-style-type: none"> The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600100_-Rev-D-IFU-NeuMoDx-WASH-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 58)</p> <ul style="list-style-type: none"> The NeuMoDx WASH Solution is a proprietary reagent that removes unbound/non-specifically bound moieties including PCR inhibitors from the magnetic microspheres bound with nucleic acid. It is formulated to work with the proprietary NeuMoDx Extraction Plate reagents to enable the removal of unnecessary material while leaving the desired nucleic acid bound to the magnetic microspheres. The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600146_D-IFU-NeuMoDx-LDT-Master-Mix-RNA-US-ONLY (Exhibit 62)</p> <ul style="list-style-type: none"> “NeuMoDx™ LDT Master Mix, RNA: Instructions for Use...Upon lysis, the released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound RNA is eluted using NeuMoDx™ RELEASE Solution.” <p>40600145_-Rev-D-IFU-NeuMoD-LDT-Master-Mix-DNA-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 67)</p> <ul style="list-style-type: none"> “NeuMoDx™ LDT Master Mix, DNA: Instructions for Use...Upon lysis, the released nucleic acids


Claim	Claim Language	Infringement Evidence
		<p>are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound DNA is eluted using NeuMoDx™ RELEASE Solution.”</p> <p>40600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 20)</p> <ul style="list-style-type: none"> • The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution. <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> • “NeuMoDx™ Cartridge: Instructions for Use...The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound nucleic acid is eluted using the NeuMoDx™ RELEASE Solution.” <p>40600129_D-IFU-GBS-Test-Strip-US-only.pdf (Exhibit 60)</p> <ul style="list-style-type: none"> • “NeuMoDx™ GBS Test Strip: Instructions for Use...The released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are loaded in to the NeuMoDx™ Cartridge where the unbound, non-DNA components are further washed away with NeuMoDx™ WASH Solution and the bound DNA is eluted using NeuMoDx™ RELEASE Solution.” <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> • Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated

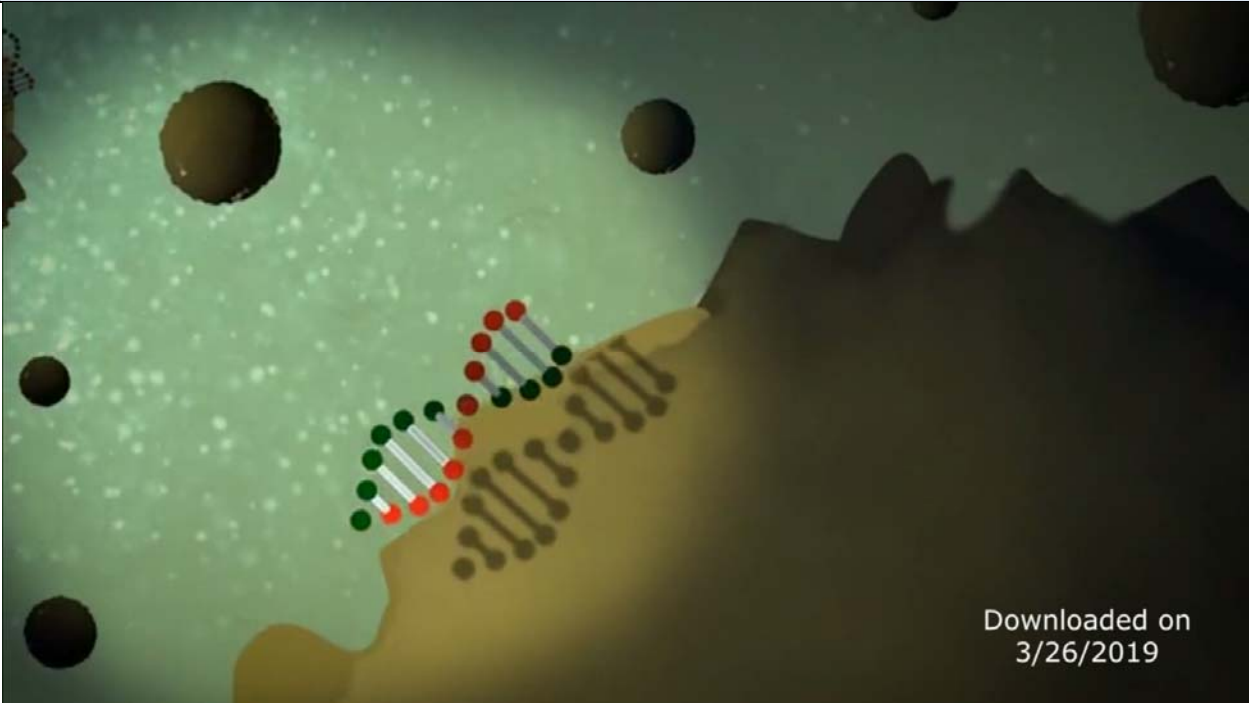
Claim	Claim Language	Infringement Evidence
		<p>microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 19. A method for nucleic acid isolation from a biological sample, comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution includes a set of affinity moiety-coated microparticles, comprising a set of microparticles amide-bonded to at least one of poly(allylamine) of molecular weight <30,000 Da and Polypropylenimine tetramine dendrimer Generation 1; producing a moiety-sample mixture upon combination of the binding moiety solution with the biological sample; producing a set of moiety-bound nucleic acid particles upon incubation of the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of the set of pins includes reversing displacement of at least one pin of the first subset of the set of pins, and reversing occlusion of a portion of the fluidic pathway. • U.S. Patent No. 9,382,532 at col. 7:54-58 (“Step S150 recites washing the moiety-bound nucleic acid volume, and functions to enable the removal of non-specifically bound moieties and to facilitate a subsequent buffer change in Step S160 by displacing any liquid retained during Step S140.”) • U.S. Patent No. 9,382,532 at col. 7:64-8:5 (“Preferably, washing the moiety bound nucleic acid volume comprises delivering a wash solution to the moiety-bound nucleic acid volume and removing the

Claim	Claim Language	Infringement Evidence
		<p>wash solution and any elements carried in the wash solution; however, washing the moiety-bound nucleic acid volume can alternatively comprise delivering a wash solution through a vessel containing the moiety-bound nucleic acid volume, in order to wash the moiety-bound nucleic acid volume in a flow-through manner.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,382,532 at col. 8:10-16 (“The wash solution preferably has a pH less than 9 and comprises purified water (e.g., Ultrapure water, deionized water) and a suitable buffer (e.g., pH 8.0 Tris buffer), but can alternatively comprise any other Suitable component or combination of components for washing the moiety-bound nucleic acid volume, as dependent upon the biological sample type.”) U.S. Patent No. 9,382,532 at col. 8:41-55 (“In a variation of the first example of Step S150, a system (such as the one described in U.S. patent application Ser. No. 13/766,359, entitled “System and Method for Processing and Detecting Nucleic Acids) can be used to deliver the wash solution into a fluidic pathway of a cartridge (such as the one described in U.S. patent application Ser. No. 13/765,996, entitled “Microfluidic Cartridge for Processing and Detecting Nucleic Acids”). In the variation of the first example, the microparticles of the moiety-bound nucleic acid volume can be retained by a magnetic field within a portion of the fluidic pathway upon occlusion of the fluidic pathway at a suitable set of occlusion positions, and the wash solution can be delivered through the portion of the fluidic pathway and into a waste chamber of the cartridge to wash the microparticles with the bound target nucleic acid(s).”) <p>US9540636 (Exhibit 54)</p> <ul style="list-style-type: none"> Claim 1: A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; and washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in

Claim	Claim Language	Infringement Evidence
		<p>coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway.”</p> <ul style="list-style-type: none"> • Claim 17: A method for nucleic acid isolation from a biological sample, comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution includes a set of affinity moiety-coated microparticles; producing a moiety-sample mixture upon combination of the binding moiety solution with the biological sample; producing a set of moiety-bound nucleic acid particles upon incubation of the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles; occluding a fluidic pathway of a cartridge upon displacement of a first subset of pin at the cartridge comprising the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles, within the fluidic pathway of the cartridge; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution. • U.S. Patent No. 9,540,636 at Abstract (“A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, in order to produce a moiety-sample mixture; incubating the moiety-sample mixture during a time window, thereby producing a solution comprising a set of moiety-bound nucleic acid particles and a waste volume; separating the set of moiety-bound nucleic acid particles from the waste volume; washing the set of moiety-bound nucleic acid particles; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles. The method preferably utilizes a binding moiety comprising at last one of poly(allylamine) and polypropylenimine tetramine dendrimer, both of which reversibly bind and unbind to nucleic acids based upon environmental pH.”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 3:28-33 (“A heating and cooling subsystem 150, a magnet 160, and a valve actuation subsystem 170 of the molecular diagnostic module 130 then facilitate separation of a set of nucleic acids from the magnetic bead-samples, as the liquid handling system 250 dispenses wash solutions, release solutions, and/or air at appropriate stages.”) • U.S. Patent No. 9,050,594 at 25:42-64 (“The syringe pump 265 of the liquid handling system 250 is coupled to a wash solution source 266, a release solution source 267, a source of air 268, and flexible tubing 291, and functions to deliver a wash solution, a release solution, and air through a

Claim	Claim Language	Infringement Evidence
		<p>valve to the molecular diagnostic module 130 to facilitate isolation and purification of nucleic acids from a set of magnetic bead-samples. The flexible tubing 291 is preferably coupled at a first end to the syringe pump, and at a second end to a nozzle 149 coupled to the linear actuator 146 of the molecular diagnostic module 130, as shown in FIG. 14C. As stated earlier, an extended configuration 146 b of the linear actuator 146 is configured to couple the nozzle 149 to a fluid port 222 of a microfluidic cartridge 210 within the molecular diagnostic module 130, such that the wash solution, release solution, and air can be delivered to the microfluidic cartridge 210 at appropriate stages. A specific embodiment of the syringe pump 265 comprises a 4-way valve, is able to pump 20-5000 μL of fluids or air through the 4-way valve at flow rates from 50-500 μL/min, can couple to syringes with between 1 mL and 10 mL capacities, and has a precision of at least 5% with regard to fluid or air delivery. Alternatively, the syringe pump 265 may be any appropriate syringe pump 265 or fluid delivery apparatus configured to deliver a wash solution, a release solution, and air to the molecular diagnostic module 130, as is readily known by those skilled in the art.”)</p>
1(o)	introducing a release solution into the first processing region,	<p>The accused workflow comprises introducing a release solution into the first processing region.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “A high pH NeuMoDx release reagent is dispensed into the S channel to cover the beads and heat is applied to complete the denaturation process, resulting in released nucleic acid or eluent.” 2:55-58 • 2:58 Release reagent

Claim	Claim Language	Infringement Evidence
		<div></div> <ul style="list-style-type: none">• 3:04 Heat/denaturation

Claim	Claim Language	Infringement Evidence
		 <p data-bbox="1675 829 1885 894">Downloaded on 3/26/2019</p> <ul style="list-style-type: none"> <li data-bbox="653 935 2011 1114">• A precise volume of air is then applied to remove any remaining liquid into the waste chamber. NeuMoDx wash solution is pumped via the fluid port into the microfluidic cartridge to remove all unbound material, followed by another volume of air to remove excess wash solution. High pH NeuMoDx release reagent is dispensed into the s-channel to cover the beads, and heat is applied to the denaturation process, resulting in released nucleic acid or eluate.” <i>Id.</i> at 2:39-3:12. <p data-bbox="604 1149 1604 1182">40600146_D-IFU-NeuMoDx-LDT-Master-Mix-RNA-US-ONLY (Exhibit 62)</p> <ul style="list-style-type: none"> <li data-bbox="653 1190 2011 1369">• “NeuMoDx™ LDT Master Mix, RNA Instructions for Use...Upon lysis, the released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound RNA is eluted using NeuMoDx™ RELEASE Solution.”

Claim	Claim Language	Infringement Evidence
		<p>40600145_-Rev-D-IFU-NeuMoD-LDT-Master-Mix-DNA-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 67)</p> <ul style="list-style-type: none"> “NeuMoDx™ LDT Master Mix, DNA Instructions for Use... Upon lysis, the released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound DNA is eluted using NeuMoDx™ RELEASE Solution.” <p>40600094_D-IFU-NeuMoDx-Cartidge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> “NeuMoDx™ Cartridge Instructions for Use... The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound nucleic acid is eluted using the NeuMoDx™ RELEASE Solution.” <p>40600129_D-IFU-GBS-Test-Strip-US-only.pdf (Exhibit 60)</p> <ul style="list-style-type: none"> “NeuMoDx™ GBS Test Strip Instructions for Use... The released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are loaded in to the NeuMoDx™ Cartridge where the unbound, non-DNA components are further washed away with NeuMoDx™ WASH Solution and the bound DNA is eluted using NeuMoDx™ RELEASE Solution.” <p>40600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 20)</p> <ul style="list-style-type: none"> “NeuMoDx™ Release Reagent Instructions for Use... NeuMoDx™ Release Solution is a proprietary reagent that releases captured nucleic acid from NeuMoDx™ proprietary affinity magnetic microspheres providing the eluate at the proper pH for mixing the dried reagents in a NeuMoDx™ test strip and subsequent Real-Time PCR.” “The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx Wash Reagent and the bound nucleic acid is eluted using NeuMoDx Release Solution.” <i>Id.</i> <p>US9050594 (Exhibit 24)</p>

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. U.S. Patent No. 9,050,594 at 3:28-33 (“A heating and cooling subsystem 150, a magnet 160, and a valve actuation subsystem 170 of the molecular diagnostic module 130 then facilitate separation of a set of nucleic acids from the magnetic bead-samples, as the liquid handling system 250 dispenses wash solutions, release solutions, and/or air at appropriate stages.”) U.S. Patent No. 9,050,594 at col. 10:49-52 (“The cartridge heater 153 functions to transfer heat to a heating region 224 of a microfluidic cartridge 210, for inducing a pH shift to release bound nucleic acids from magnetic beads within the heating region 224.”) U.S. Patent 9,050,594 at col. 29:57-30:7 (“Preferably, Step S443 comprises defining at least one truncated fluidic pathway coupled to a waste chamber and to a fluid port, which functions to facilitate washing of at least one nucleic acid-magnetic bead sample in the set of nucleic acid-magnetic bead samples, and releasing of at least one nucleic acid volume from the set of nucleic acid-magnetic bead samples. Step S440 may additionally comprise delivering a wash solution through a portion of at least one fluidic pathway S444, such as the truncated fluidic pathway defined in Step S443, and delivering a release solution through a portion of at least one fluidic pathway S445, such as the truncated fluidic pathway defined in Step S443. Step S444 functions to wash at least one nucleic acid-magnetic bead sample in the set of nucleic acid-magnetic bead samples, and Step S445 functions to release at least one nucleic acid volume from the set of nucleic acid-magnetic bead samples. The heater provided in Step S442 may be activated after Step S445 to induce a pH shift.”) <p>US9339812 (Exhibit 26)</p> <ul style="list-style-type: none"> Claim 7. The method of claim 6, wherein separating the volume of nucleic acids from the biological

Claim	Claim Language	Infringement Evidence
		<p>sample further comprises dispensing a release solution through the fluidic pathway by the fluid port.</p> <ul style="list-style-type: none"> • Claim 8. The method of claim 7, wherein separating the volume of nucleic acids from the biological sample further comprises heating the first portion of the fluidic pathway to facilitate a pH shift, thus releasing nucleic acids from magnetic beads to produce the volume of nucleic acids. • Claim 20. The method of claim 19, wherein producing the set of nucleic acid volumes from the set of nucleic acid-magnetic bead samples comprises: upon passing a magnet through one of the set of slots of the cartridge platform of the molecular diagnostic module, providing a magnetic field spanning a portion of each fluidic pathway in the set of fluidic pathways, thus capturing the set of nucleic acid-magnetic bead samples; dispensing a wash solution into each fluidic pathway of the set of fluidic pathways; dispensing a release solution into each fluidic pathway of the set of fluidic pathways; and heating each fluidic pathway of the set of fluidic pathways to facilitate a pH shift, thus unbinding nucleic acids from magnetic beads to produce the set of nucleic acid volumes. • U.S. Patent No. 9,339,812 at col.10:49-52 (“The cartridge heater functions to transfer heat to a heating region of a microfluidic cartridge, for inducing a pH shift to release bound nucleic acids from magnetic beads within the heating region.”) • U.S. Patent NO. 9,339,812 at col. 25:43-49 (“The syringe pump 265 of the liquid handling system 250 is coupled to a wash solution source 266, a release solution source 267, a source of air 268, and flexible tubing 291, and functions to deliver a wash solution, a release solution, and air through a valve to the molecular diagnostic module 130 to facilitate isolation and purification of nucleic acids from a set of magnetic bead-samples.”) • U.S. Patent No. 9,339,812 at col. 29:50-53 (“Step S442 functions to provide a heater, which, in combination with a release solution that provides a pH shift, facilitate a rapid and efficient unbinding of the nucleic acids from magnetic beads.”) <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> • Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to

Claim	Claim Language	Infringement Evidence
		<p>reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 12. The method of claim 1, further comprising releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles, wherein releasing the nucleic acid sample comprises contacting the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH that is greater than pH 10. • Claim 13: The method of claim 3, wherein releasing the nucleic acid sample from the set of moiety-bound nucleic acid particles comprises occluding the fluidic pathway of the cartridge, comprising the process chamber, at a set of occlusion positions, upon displacement of pins of the set of pins, to define a path through a magnetic field; delivering the set of moiety-bound nucleic acid particles into the path of the fluidic pathway; and delivering an elution solution into the fluidic pathway, thereby inducing a pH shift configured to release the nucleic acid sample from the set of moiety-bound nucleic acid particles.” • Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a

Claim	Claim Language	Infringement Evidence
		<p>set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the microfluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20 uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction.</p> <div data-bbox="716 581 1507 933" data-label="Diagram"> </div> <p style="text-align: center;">FIGURE 1C</p> <ul style="list-style-type: none"> U.S. Patent No. 9,382,532 at 8:56-9:1 (“Step S160 recites releasing a nucleic acid sample from the moiety-bound nucleic acid volume, and functions to separate the microparticles from the bound nucleic acid of the moiety-bound nucleic acid volume by using a reagent (i.e., an elution solution) that mitigates the affinity of the coated microparticles for the target nucleic acid(s) and creates an environment for the release of the target nucleic acid(s) from the microparticles. Preferably, Step S160 enables the elution/release of as much of the bound target nucleic acids in the fastest amount of time; however, Step S160 can alternatively or additionally enable the elution/release of as much of the bound target nucleic acids using the smallest volume of elution solution or any other suitable limiting parameter.”) U.S. Patent No. 9,382,532 at col. 9:9-24 (“In one variation of Step S160, the affinity moieties,

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		<p>examples of which are described in Section 2 below, function based upon the pH of the environment. Specifically, at low pH, the affinity moieties are positively charged, which results in attraction to negatively charged nucleic acids; however, at high pH, the affinity moieties are negatively charged, which results in repulsion of negatively charged nucleic acids. In a specific example of this variation, releasing the nucleic acid sample comprises providing an elution solution that is in the range of pH 12-pH 13 to effect efficient elution/release of the bound target nucleic acid(s) from the microparticle based upon a shift to a more basic pH. In the specific example, the elution solution comprises 20 mM of NaOH; however, in other variations the elution Solution can comprise any other suitable concentration of NaOH or KOH, depending upon the application (e.g., sample type).”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,382,532 at col. 9:38-49 (“Preferably, an elevated temperature in combination with an elevated pH resulting from the elution solution provides the enhanced conditions to facilitate the release of the nucleic acid sample. Furthermore, an elevated temperature (e.g., elevating a sample eluted at room temperature to 85 C) can function to minimize protease enzyme activity in the eluted nucleic acid and thereby improve the robustness of the detection of the target nucleic acid sample during processing in variations of Step S110; however, the method 100 can alternatively omit Step S161 in applications wherein heating the moiety-bound nucleic acid Volume is undesirable and/or unnecessary.”) <p>US9540636 (Exhibit 54)</p> <ul style="list-style-type: none"> Claim 17: A method for nucleic acid isolation from a biological sample, comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution includes a set of affinity moiety-coated microparticles; producing a moiety-sample mixture upon combination of the binding moiety solution with the biological sample; producing a set of moiety-bound nucleic acid particles upon incubation of the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles; occluding a fluidic pathway of a cartridge upon displacement of a first subset of pin at the cartridge comprising the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles, within the fluidic pathway of the cartridge; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution. Claim 12. The method of claim 1, further comprising releasing a nucleic acid sample from the set of

Claim	Claim Language	Infringement Evidence
		<p>moiety-bound nucleic acid particles, wherein releasing the nucleic acid sample comprises contacting the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH that is greater than pH 10.</p> <ul style="list-style-type: none"> • Claim 17: A method for nucleic acid isolation from a biological sample, comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution includes a set of affinity moiety-coated microparticles; producing a moiety-sample mixture upon combination of the binding moiety solution with the biological sample; producing a set of moiety-bound nucleic acid particles upon incubation of the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles; occluding a fluidic pathway of a cartridge upon displacement of a first subset of pin at the cartridge comprising the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles, within the fluidic pathway of the cartridge; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution. • U.S. Patent No. 9,540,636 at col. 9:34-42 (“In a specific example of this variation, releasing the nucleic acid sample comprises providing an elution solution that is in the range of pH 12-pH 13 to effect efficient elution/release of the bound target nucleic acid(s) from the microparticle based upon a shift to a more basic pH. In the specific example, the elution solution comprises 20 mM of NaOH; however, in other variations the elution solution can comprise any other suitable concentration of NaOH or KOH, depending upon the application (e.g., sample type).”) • U.S. Patent No. 9,540,636 at col. 9:56-67 (“Preferably, an elevated temperature in combination with an elevated pH resulting from the elution solution provides the enhanced conditions to facilitate the release of the nucleic acid sample. Furthermore, an elevated temperature (e.g., elevating a sample eluted at room temperature to 85 C) can function to minimize protease enzyme activity in the eluted nucleic acid and thereby improve the robustness of the detection of the target nucleic acid sample during processing in variations of Step S170; however, the method 100 can alternatively omit Step S161 in applications wherein heating the moiety-bound nucleic acid Volume is undesirable and/or unnecessary.”) • U.S. Patent No. 9,540,636 at col. 10:3-14 (“In an example of Step S161, heating comprises elevating the temperature of the moiety-bound nucleic acid volume to 80-85 C, for 3 minutes, and in another example, heating comprises elevating the temperature of the moiety-bound nucleic acid volume to 50-70 C, for 3-10 minutes. In other examples, the elevation temperature can be maintained at a desired set

Claim	Claim Language	Infringement Evidence
		<p>point for as low as 1 minute or as high as 30 minutes. Further, elution conditions may be optimized to ensure that the bound nucleic acid is only eluted in the presence of the high pH solution at the elevated temperature for a specified amount of time.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 14:22-28 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 500 uL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 30:60-61 (“ELUTION SOLUTION ELU-2 40 mM NaOH: ultrapure water (960 mL) and 1N NaOH (40 mL).”) • U.S. Patent No. 9,540,636 at col. 14:57-63 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 250 uL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 15:31-36 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL or 250 uL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 15:67-16:6 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 16:57-64 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-1 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 30:58-59 (“ELUTION SOLUTION ELU-1 20 mM NaOH: ultrapure water (980 mL) and 1N NaOH (20 mL).”) • U.S. Patent No. 9,540,636 at col. 17:29-34 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 17:66-18: (“Upon removal of the unbound supernatant in an example

Claim	Claim Language	Infringement Evidence
		<p>of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the magnetic microparticles to 85 C for 3 minutes in an example of Step S160.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 18:37-43 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 19:13-19 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 19:51-57 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed twice with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 20:37-43 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 21:9-16 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160. DNA was eluted into 10 uL of ELU-2 and 2 uL of the eluate was used for real-time PCR in an example of Step S110.”) • U.S. Patent No. 9,540,636 at col. 21:42-48 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 22:5-11 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by

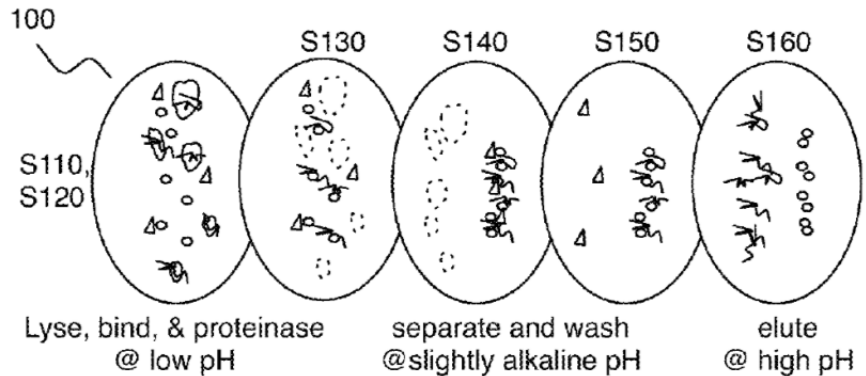
Claim	Claim Language	Infringement Evidence
		<p>using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 22:67-23:7 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 23:42-48 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 or ELU-3 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 30:62-63 (“ELUTION SOLUTION ELU-3 40 mM KOH: ultrapure water (960 mL) and 1N KOH (40 mL).”) • U.S. Patent No. 9,540,636 at col. 24:23-29 (“Upon removal of the unbound Supernatant in an example of Step S140, the PAA affinity moieties coated onto magnetic microparticles were washed twice (2x) with 500 uL of WSH-1 solution in an example of Step S150, and then the captured RNA and DNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”) <p>US10010888 (Exhibit 55)</p> <ul style="list-style-type: none"> • Claim 17. The method of claim 14, further comprising delivering a release solution into the fluidic pathway, thereby producing a nucleic acid volume from the nucleic acid-magnetic bead sample. • U.S. Patent No. 10,010,888 at col. 11:7-10 (“The cartridge heater 153 functions to transfer heat to a heating region 224 of a microfluidic cartridge 210, for inducing a pH shift to release bound nucleic acids from magnetic beads within the heating region 224.”) U.S. Patent No. 10,010,888 at col. 34:4-11 (“In embodiments wherein multiple heaters are provided, each heater is preferably independent to allow independent control of heating time and temperature for each sample. Step S442 functions to provide a heater, which, in combination with a release solution that provides a pH shift, facilitates a rapid and efficient unbinding of the nucleic acids from the magnetic beads.”)
1(p)	wherein the release solution has a pH of at least 10.5;	The accused workflow comprises introducing a release solution into the first processing region, wherein the release solution has a pH of at least 10.5.

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		<p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none">“A high pH NeuMoDx release reagent is dispensed into the S channel to cover the beads and heat is applied to complete the denaturation process, resulting in released nucleic acid or eluent.” 2:55-3:10 <p>40600114_Rev-C-SDS-NeuMoDx-Release-Solution-FINAL.pdf (Exhibit 78)</p> <table><tr><th colspan="4">Hazardous chemical ingredients per U.S. OSHA criteria (29 CFR 1910.1200 Hazard Communication):</th></tr><tr><th>Chemical Name</th><th>Identifiers</th><th>Classification</th><th>Concentration Percentages are by weight</th></tr><tr><td>Sodium Hydroxide (NaOH)</td><td>CAS-No. 1310-73-2 EC-No. 215-185-5 Index-No. 011-002-00-6 Registration No. 01-2119457892-27-XXXX</td><td>Metal Corrosive 1; Skin Corrosive 1B; Eye Damage 1; Aquatic Acute 3; H290, H314, H318, H402.</td><td><1% /</td></tr><tr><td>Deionized water</td><td>CAS-No. 7732-18-5</td><td>N/A</td><td>>99%</td></tr></table> <p>Odor: Odorless</p> <p>pH Value at 20°C (68°F) 11.8-12.8</p> <p>US9339812 (Exhibit 26)</p> <ul style="list-style-type: none">Claim 7. The method of claim 6, wherein separating the volume of nucleic acids from the biological sample further comprises dispensing a release solution through the fluidic pathway by the fluid port.Claim 8. The method of claim 7, wherein separating the volume of nucleic acids from the biological sample further comprises heating the first portion of the fluidic pathway to facilitate a pH shift, thus releasing nucleic acids from magnetic beads to produce the volume of nucleic acids.Claim 20. The method of claim 19, wherein producing the set of nucleic acid volumes from the set of	Hazardous chemical ingredients per U.S. OSHA criteria (29 CFR 1910.1200 Hazard Communication):				Chemical Name	Identifiers	Classification	Concentration Percentages are by weight	Sodium Hydroxide (NaOH)	CAS-No. 1310-73-2 EC-No. 215-185-5 Index-No. 011-002-00-6 Registration No. 01-2119457892-27-XXXX	Metal Corrosive 1; Skin Corrosive 1B; Eye Damage 1; Aquatic Acute 3; H290, H314, H318, H402.	<1% /	Deionized water	CAS-No. 7732-18-5	N/A	>99%
Hazardous chemical ingredients per U.S. OSHA criteria (29 CFR 1910.1200 Hazard Communication):																		
Chemical Name	Identifiers	Classification	Concentration Percentages are by weight															
Sodium Hydroxide (NaOH)	CAS-No. 1310-73-2 EC-No. 215-185-5 Index-No. 011-002-00-6 Registration No. 01-2119457892-27-XXXX	Metal Corrosive 1; Skin Corrosive 1B; Eye Damage 1; Aquatic Acute 3; H290, H314, H318, H402.	<1% /															
Deionized water	CAS-No. 7732-18-5	N/A	>99%															

Claim	Claim Language	Infringement Evidence
		<p>nucleic acid-magnetic bead samples comprises: upon passing a magnet through one of the set of slots of the cartridge platform of the molecular diagnostic module, providing a magnetic field spanning a portion of each fluidic pathway in the set of fluidic pathways, thus capturing the set of nucleic acid-magnetic bead samples; dispensing a wash solution into each fluidic pathway of the set of fluidic pathways; dispensing a release solution into each fluidic pathway of the set of fluidic pathways; and heating each fluidic pathway of the set of fluidic pathways to facilitate a pH shift, thus unbinding nucleic acids from magnetic beads to produce the set of nucleic acid volumes.</p> <ul style="list-style-type: none"> U.S. Patent No. 9,339,812 at col.10:49-52 (“The cartridge heater functions to transfer heat to a heating region of a microfluidic cartridge, for inducing a pH shift to release bound nucleic acids from magnetic beads within the heating region.”) U.S. Patent No. 9,339,812 at col. 29:50-53 (“Step S442 functions to provide a heater, which, in combination with a release solution that provides a pH shift, facilitate a rapid and efficient unbinding of the nucleic acids from magnetic beads.”) <p>US9540636 (Exhibit 54)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,540,636 at col.14:22-28 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 500 uL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) U.S. Patent No. 9,540,636 at col. 30:60-61 (“ELUTION SOLUTION ELU-2 40 mM NaOH: ultrapure water (960 mL) and 1N NaOH (40 mL).”) U.S. Patent No. 9,540,636 at col. 14:57-63 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 250 uL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) U.S. Patent No. 9,540,636 at col. 15:31-36 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL or 250 uL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”) U.S. Patent No. 9,540,636 at col.15:67-16:6 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity

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		<p>matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 30:58-59 (“ELUTION SOLUTION ELU-1 20 mM NaOH: ultrapure water (980 mL) and 1N NaOH (20 mL).”) • U.S. Patent No. 9,540,636 at col. 17:29-34 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 17:66-18: (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the magnetic microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 18:37-43 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 19:13-19 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 19:51-57 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed twice with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 20:37-43 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 21:9-16 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160. DNA was eluted into 10 uL of ELU-2

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		<p>and 2 uL of the eluate was used for real-time PCR in an example of Step S110.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 21:42-48 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 22:5-11 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 22:67-23:6 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 23:42-48 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 or ELU-3 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 30:62-63 (“ELUTION SOLUTION ELU-3 40 mM KOH: ultrapure water (960 mL) and 1N KOH (40 mL).”) • U.S. Patent No. 9,540,636 at col. 25:23-29 (“Upon removal of the unbound Supernatant in an example of Step S140, the PAA affinity moieties coated onto magnetic microparticles were washed twice (2x) with 500 uL of WSH-1 solution in an example of Step S150, and then the captured RNA and DNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”) <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> • Claim 15. The method of claim 1, wherein releasing the nucleic acid sample from the set of moiety-bound nucleic acid particles comprises contacting the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH that is in the range of pH 10 to pH 13. • Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding

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		<p>moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the microfluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20 uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction.</p>  <p style="text-align: center;">FIGURE 1C</p> <ul style="list-style-type: none"> U.S. Patent No. 9,382,532 at col. 9:9-24 (“In one variation of Step S160, the affinity moieties, examples of which are described in Section 2 below, function based upon the pH of the

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		<p>environment. Specifically, at low pH, the affinity moieties are positively charged, which results in attraction to negatively charged nucleic acids; however, at high pH, the affinity moieties are negatively charged, which results in repulsion of negatively charged nucleic acids. In a specific example of this variation, releasing the nucleic acid sample comprises providing an elution solution that is in the range of pH 12-pH 13 to effect efficient elution/release of the bound target nucleic acid(s) from the microparticle based upon a shift to a more basic pH. In the specific example, the elution solution comprises 20 mM of NaOH: however, in other variations the elution Solution can comprise any other suitable concentration of NaOH or KOH, depending upon the application (e.g., sample type).”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at col. 9:38-49 (“Preferably, an elevated temperature in combination with an elevated pH resulting from the elution Solution provides the enhanced conditions to facilitate the release of the nucleic acid sample. Furthermore, an elevated temperature (e.g., elevating a sample eluted at room temperature to 85 C) can function to minimize protease enzyme activity in the eluted nucleic acid and thereby improve the robustness of the detection of the target nucleic acid sample during processing in variations of Step S110; however, the method 100 can alternatively omit Step S161 in applications wherein heating the moiety-bound nucleic acid Volume is undesirable and/or unnecessary.”) • U.S. Patent No. 9,382,532 at col. 14:54-61 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL or 250 uL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160. RNA was eluted into 10 uL of ELU-2 and 8 uL of the eluate was used for real-time RT-PCR in an example of Step 170.”) • U.S. Patent No. 9,382,532 at col. 28:64-65 (“Elution Solution ELU-2 - 40 mM NaOH: ultrapure water (960 mL) and 1N NaOH (40 mL).”) • U.S. Patent No. 9,382,532 at 15:19-26 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160. RNA was eluted into 10 uL of ELU-2 and 2 LL of the eluate was used for real-time RT-PCR in an example of Step S170.”) • U.S. Patent No. 9,382,532 at 16:2-14 (“DNA was allowed to bind to the DABAM affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature or 60 C depending on matrix

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		<p>used in examples of Step S130. Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-1 and heating the microparticles to 85 C for 3 minutes in an example of Step S160. DNA was eluted into 10 uL of ELU-1 and 8 ul of the eluate was used for real-time PCR in an example of Step S170.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at 28:62-63 (“Elution Solution ELU-1 - 20 mM NaOH: ultrapure water (980 mL) and 1N NaOH (20 mL).”) • U.S. Patent No. 9,382,532 at 16:38-44 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500LL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at 17:4-10 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the magnetic microparticles to 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at 17:37-43 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at col. 18:8-16 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160. DNA was eluted into 10 uL of ELU-2 and 2 ul of the eluate was used for real-time PCR in an example of Step S170.”) • U.S. Patent No. 9,382,532 at col. 18:41-47 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed twice with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at 19:22-27 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using

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		<p>ELU-2 at 85 C for 3 minutes in an example of Step S160.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at 19:56-61 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500LL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at 20:17-32 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at col. 21:34-39 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500LL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at col. 22:2-8 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 or ELU-3 and heating the microparticles to 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at col. 28:66-67 (“Elution Solution ELU-3–40 mM KOH: ultrapure water (960 mL) and 1N KOH (40 mL).”)
1(q)	heating the first processing region to a second temperature greater than the first temperature, wherein at least a portion of the polynucleotides are eluted form the plurality of magnetic binding particles into an eluate solution; and	<p>The accused workflow comprises heating the first processing region to a second temperature greater than the first temperature, wherein at least a portion of the polynucleotides are eluted form the plurality of magnetic binding particles into an eluate solution.</p> <p>On information and belief, the accused system comprises heating the first processing region to a second temperature greater than the first temperature, wherein at least a portion of the polynucleotides are eluted form the plurality of magnetic binding particles into an eluate solution.</p> <p>US9540636 (Exhibit 54)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col.14:22-28 (“Upon removal of the unbound Supernatant in an example


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		<p>of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 500 uL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 30:60-61 (“ELUTION SOLUTION ELU-2 40 mM NaOH: ultrapure water (960 mL) and 1N NaOH (40 mL).”) • U.S. Patent No. 9,540,636 at col. 14:57-63 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 250 uL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 15:31-36 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL or 250 uL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col.15:67-16:6 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 16:57-64 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-1 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 30:58-59 (“ELUTION SOLUTION ELU-1 20 mM NaOH: ultrapure water (980 mL) and 1N NaOH (20 mL).”) • U.S. Patent No. 9,540,636 at col. 17:29-34 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 17:66-18:5 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the magnetic microparticles to 85 C for 3 minutes in an example of Step S160.”)

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		<ul style="list-style-type: none"> • U.S. Patent No. 9,540,636 at col. 18:37-43 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 19:13-19 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 19:51-57 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed twice with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 20:37-43 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 21:9-16 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160. DNA was eluted into 10 uL of ELU-2 and 2 uL of the eluate was used for real-time PCR in an example of Step S110.”) • U.S. Patent No. 9,540,636 at col. 21:42-48 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 22:5-11 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,540,636 at col. 22:67-23:6 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity

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		<p>matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,540,636 at col. 23:42-48 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 or ELU-3 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) U.S. Patent No. 9,540,636 at col. 30:62-63 (“ELUTION SOLUTION ELU-3 40 mM KOH: ultrapure water (960 mL) and 1N KOH (40 mL).”) U.S. Patent No. 9,540,636 at col. 24:23-29 (“Upon removal of the unbound Supernatant in an example of Step S140, the PAA affinity moieties coated onto magnetic microparticles were washed twice (2x) with 500 uL of WSH-1 solution in an example of Step S150, and then the captured RNA and DNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”) <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,382,532 at col. 14:54-61 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL or 250 uL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160. RNA was eluted into 10 uL of ELU-2 and 8 uL of the eluate was used for real-time RT-PCR in an example of Step 170.”) U.S. Patent No. 9,382,532 at col. 28:64-65 (“Elution Solution ELU-2 - 40 mM NaOH: ultrapure water (960 mL) and 1N NaOH (40 mL).”) U.S. Patent No. 9,382,532 at 15:19-26 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 100 uL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160. RNA was eluted into 10 uL of ELU-2 and 2 LL of the eluate was used for real-time RT-PCR in an example of Step S170.”) U.S. Patent No. 9,382,532 at 16:2-14 (“DNA was allowed to bind to the DABAM affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature or 60 C depending on matrix used in examples of Step S130. Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an

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		<p>example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-1 and heating the microparticles to 85 C for 3 minutes in an example of Step S160. DNA was eluted into 10 uL of ELU-1 and 8 ul of the eluate was used for real-time PCR in an example of Step S170.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at 28:62-63 (“Elution Solution ELU-1 - 20 mM NaOH: ultrapure water (980 mL) and 1N NaOH (20 mL).”) • U.S. Patent No. 9,382,532 at 16:38-44 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500LL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at 17:4-10 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the magnetic microparticles to 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at 17:37-43 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at col. 18:8-16 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160. DNA was eluted into 10 uL of ELU-2 and 2 ul of the eluate was used for real-time PCR in an example of Step S170.”) • U.S. Patent No. 9,382,532 at col. 18:41-47 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed twice with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at 19:22-27 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at 19:56-61 (“Upon removal of the unbound Supernatant in an example of

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		<p>Step S140, the magnetic microparticles with bound DNA were washed with 500LL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85C for 3 minutes in an example of Step S160.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at 20:17-32 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at col. 21:34-39 (“Upon removal of the unbound Supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500LL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at col. 22:2-8 (“Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 uL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 or ELU-3 and heating the microparticles to 85C for 3 minutes in an example of Step S160.”) • U.S. Patent No. 9,382,532 at col. 28:66-67 (“Elution Solution ELU-3—40 mM KOH: ultrapure water (960 mL) and 1N KOH (40 mL).”)
1(r)	transferring the eluate solution containing polynucleotides to a second processing region in the system,	<p>The accused workflow comprises transferring the eluate solution containing polynucleotides to a second processing region in the system.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936 (Exhibit 16)</p> <ul style="list-style-type: none"> • “Liquid Handling Processing C: The Test Strip. After piercing the test strip, the liquid handling robot moves to the PCR port or p-port of the microfluidic cartridge, where it aspirates the eluate out of the cartridge into the pipette tip. Once the aspiration step is complete, the eluate is delivered to the appropriate wells in the NeuMoDx test strip, where it is dispensed and aspirated ten times to ensure homogeneous resuspension of the NeuDry PCR reagents. The sample mixes with primers and probes.” <i>Id.</i> at 3:12-3:36 • 3:36 test strip

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		 <p data-bbox="604 1003 2032 1040">40600145_-Rev-D-IFU-NeuMoD-LDT-Master-Mix-DNA-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 67)</p> <ul data-bbox="653 1040 2032 1409" style="list-style-type: none"> • Upon lysis, the released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound DNA is eluted using NeuMoDx™ RELEASE Solution. The NeuMoDx System mixes the released DNA with the user provided LDT primers and probe(s) and then uses an aliquot of this solution to rehydrate the dried assay reagents in the NeuMoDx LDT MM Test Strip, DNA, which contains all the reagents necessary to perform a real-time PCR- specifically Taq DNA polymerase, dNTPS, MgCl₂ and other optimized excipients and buffering agents. 40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19) • The NeuMoDx Systems mix the released nucleic acid with assay specific primers and probe(s) as

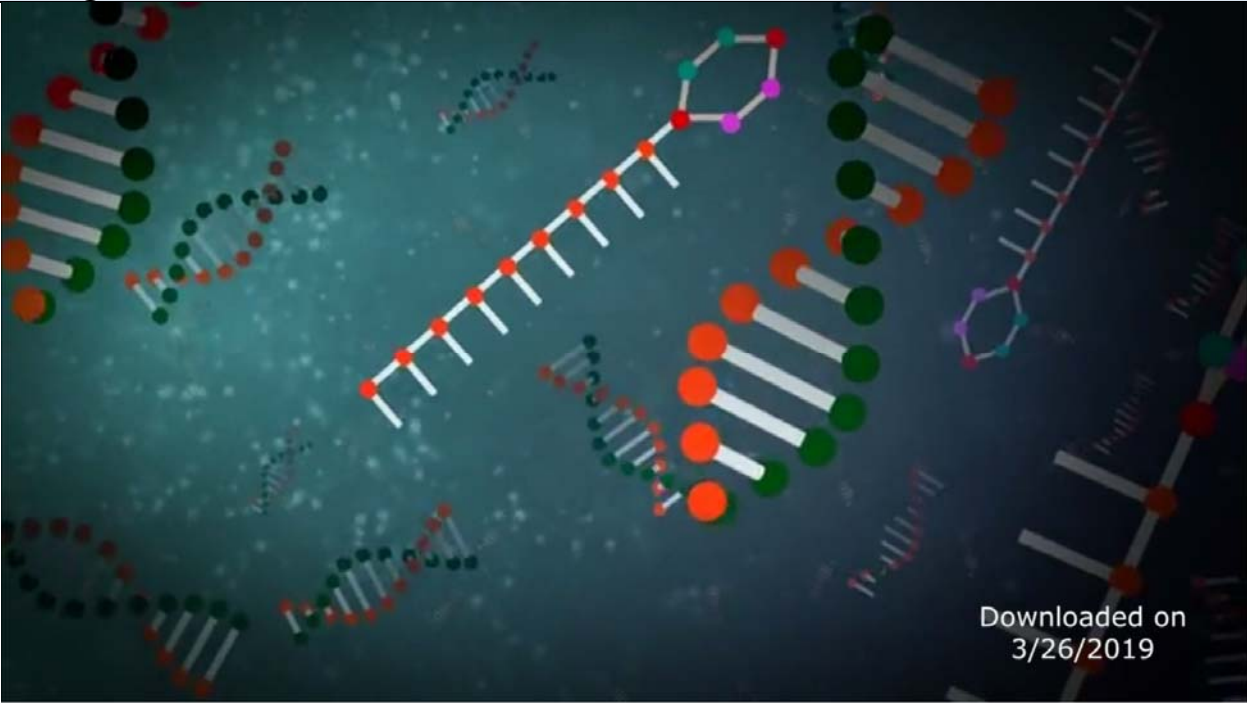
Claim	Claim Language	Infringement Evidence
		<p>well as the dried Master Mix contained in a NeuMoDx test strip. The system then dispenses the prepared PCR-ready mixture into the NeuMoDx Cartridge where Real-Time PCR occurs.</p> <p>40600106_Rev-D-IFU-NeuMoDx-Lysis-Buffer-1-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 63)</p> <ul style="list-style-type: none"> The NeuMoDx Systems mix the released nucleic acid with assay specific primers and probe(s) as well as the dried Master Mix contained in a NeuMoDx™ test strip. The system then dispenses the prepared PCR-ready mixture into the NeuMoDx Cartridge where Real-Time PCR occurs. <p>40600105_Rev-D-IFU-NeuMoDx-Lysis-Buffer-2-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 64)</p> <ul style="list-style-type: none"> The NeuMoDx Systems mix the released nucleic acid with assay specific primers and probe(s) as well as the dried Master Mix contained in a NeuMoDx™ test strip. The system then dispenses the prepared PCR-ready mixture into the NeuMoDx Cartridge where Real-Time PCR occurs. <p>40600104_Rev-D-IFU-NeuMoDx-Lysis-Buffer-3-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 65)</p> <ul style="list-style-type: none"> The NeuMoDx Systems mix the released nucleic acid with assay specific primers and probe(s) as well as the dried Master Mix contained in a NeuMoDx™ test strip. The system then dispenses the prepared PCR-ready mixture into the NeuMoDx Cartridge where Real-Time PCR occurs. <p>40600103_Rev-D-IFU-NeuMoDx-Lysis-Buffer-4-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 66)</p> <ul style="list-style-type: none"> The NeuMoDx Systems mix the released nucleic acid with assay specific primers and probe(s) as well as the dried Master Mix contained in a NeuMoDx™ test strip. The system then dispenses the prepared PCR-ready mixture into the NeuMoDx Cartridge where Real-Time PCR occurs. <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 10. The system of claim 1, further comprising an assay strip comprising at least one reagent well, each containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume. Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-

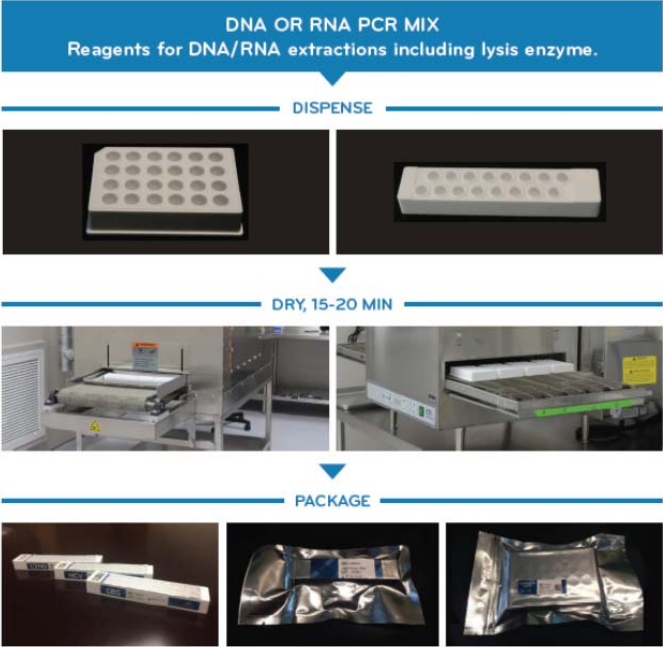
Claim	Claim Language	Infringement Evidence
		<p>sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 24. The system of claim 23, further comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample, a lysing reagent, and a sample process control, wherein the capture plate facilitates production of at least one biological sample combined with magnetic beads; an assay strip comprising at least one reagent well containing molecular diagnostic reagent volume configured to be combined with a nucleic acid volume of the set of nucleic acid volumes to produce at least one nucleic acid-reagent mixture; and a liquid handling system configured to transfer at least one biological sample combined with magnetic beads from the capture plate to the molecular diagnostic module, transfer at least one nucleic acid-reagent mixture from the assay strip back to the molecular diagnostic module. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) • U.S. Patent No. 9,050,594 at col. 3:14-46 (“In one example workflow of the system 100, a liquid handling system 250 aspirates a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), and dispenses the set of biological samples into a capture plate 110 to be lysed and

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		<p>combined with magnetic beads (containing a proprietary affinity coating to bind the nucleic acids to the magnetic beads) by a capture plate module 120. The liquid handling system 250 then aspirates substantially all of each sample of the set of lysed biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate no, and dispenses the set of magnetic bead-samples into a microfluidic cartridge 210, aligned within a cartridge receiving module 140 of a molecular diagnostic module 130, and configured to be manipulated by the molecular diagnostic module 130. A heating and cooling subsystem 150, a magnet 160, and a valve actuation subsystem 170 of the molecular diagnostic module 130 then facilitate separation of a set of nucleic acids from the magnetic bead-samples, as the liquid handling system 250 dispenses wash solutions, release solutions, and/or air at appropriate stages. The liquid handling system 250 then aspirates the set of nucleic acids from the microfluidic cartridge 210 contained within the molecular diagnostic module 130, combines the set of nucleic acids with a set of molecular diagnostic reagents using an assay strip 190, and dispenses the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the microfluidic cartridge 210 within the molecular diagnostic module 130. The detection chamber heaters 157, optical subsystem 180 and valve actuation sub-system 170 of the molecular diagnostic module 130 then facilitate analysis of the set of nucleic acid-reagent mixtures by a processor configured to display information on a user interface.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 23:41-53 (“The embodiment of the liquid handling system 100 is further configured to facilitate separation of a set of nucleic acids from the magnetic bead-samples, by dispensing a wash solution, a release solution, and/or air into the molecular diagnostic 45 module 130, by the nozzle 149 coupled to the linear actuator 146, at appropriate stages, aspirate the set of nucleic acids from the molecular diagnostic module 130, combine the set of nucleic acids with a set of molecular diagnostic reagents using an assay strip 190, and dispense the set of nucleic acids 50 combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the molecular diagnostic module 130 for further processing and analysis.”) <p>US9441219 (Exhibit 53)</p> <ul style="list-style-type: none"> Claim 7: The molecular diagnostic module of claim 1, further comprising: a capture plate comprising a well containing a set of magnetic beads, a lysing reagent, and a sample process control, configured to be combined with the biological sample, wherein the capture plate facilitates production of a magnetic bead-sample from the biological sample and the set of magnetic beads; an assay strip comprising a reagent well containing a molecular diagnostic reagent volume configured to be combined with the


Claim	Claim Language	Infringement Evidence
		<p>nucleic acid volume processed from the magnetic-bead sample, thereby generating a nucleic acid-reagent mixture; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the cartridge, transfer the nucleic acid volume from the cartridge to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip back to the cartridge.</p> <ul style="list-style-type: none"> US 9,441,219 at col. 3:41-49 (“The liquid handling system 250 then aspirates the set of nucleic acids from the micro-fluidic cartridge 210 contained within the molecular diagnostic module 130, combines the set of nucleic acids with a set of molecular diagnostic reagents using an assay strip 190, and dispenses the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the microfluidic cartridge 210 within the molecular diagnostic module 130.”) <p>US9339812 (Exhibit 26)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,339,812 at col. 3:14-46 (“The liquid handling system 250 then aspirates the set of nucleic acids from the microfluidic cartridge 210 contained within the molecular diagnostic module 130, combines the set of nucleic acids with a set of molecular diagnostic reagents using an assay strip 190, and dispenses the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the microfluidic cartridge 210 within the molecular diagnostic module 130. The detection chamber heaters 157, optical subsystem 180 and valve actuation sub-system 170 of the molecular diagnostic module 130 then facilitate analysis of the set of nucleic acid-reagent mixtures by a processor configured to display information on a user interface.”) U.S. Patent No. 9,339,812 at col. 23:32-53 (“As described in Section 1, an embodiment of the liquid handling system 250 is configured to aspirate a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), dispense the set of biological samples into a capture plate no to be lysed and combined with magnetic beads by a capture plate module 120, aspirate the set of biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate 110, and dispense the set of magnetic bead-samples into microfluidic cartridge 210 located in a molecular diagnostic module 130. The embodiment of the liquid handling system 100 is further configured to facilitate separation of a set of nucleic acids from the magnetic bead-samples, by dispensing a wash solution, a release solution, and/or air into the molecular diagnostic module 130, by the nozzle 149 coupled to the linear actuator 146, at appropriate stages, aspirate the set of nucleic acids from the molecular diagnostic module 130, combine the set of nucleic acids with a set of molecular diagnostic reagents using an assay strip 190, and dispense the set of nucleic acids combined with the

Claim	Claim Language	Infringement Evidence
		set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the molecular diagnostic module 130 for further processing and analysis.”)
1(s)	wherein the eluate solution reconstitutes PCR reagents contained in the second processing region to form a PCR-ready solution.	<p>The accused workflow comprises eluate solution that reconstitutes PCR reagents contained in the second processing region to form a PCR-ready solution.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936 (Exhibit 16)</p> <ul style="list-style-type: none"> • “Liquid Handling Processing C: The Test Strip. After piercing the test strip, the liquid handling robot moves to the PCR port or p-port of the microfluidic cartridge, where it aspirates the eluate out of the cartridge into the pipette tip. Once the aspiration step is complete, the eluate is delivered to the appropriate wells in the NeuMoDx test strip, where it is dispensed and aspirated ten times to ensure homogeneous resuspension of the NeuDry PCR reagents. The sample mixes with primers and probes.” <i>Id.</i> at 3:12-3:36 • 3:46 Primers and probes

Claim	Claim Language	Infringement Evidence
		 <p data-bbox="604 966 1312 998">NeuMoDx_Novel_Dry_Reagent_2017.pdf (Exhibit 80)</p> <ul data-bbox="653 1006 2011 1404" style="list-style-type: none"> • The rapid development in nucleic acid based testing (NAT) in diagnosis has resulted in the routine use of qPCR in molecular diagnostic labs. Reagents for such qPCR assays have typically required the need for cold or frozen storage to maintain long term viability. Not only does the need for cold temperature storage offer substantial challenges to the implementation of NAT in resource limited settings, but the need for such cold storage equipment also severely complicates the development of next generation molecular diagnostic instrumentation with onboard reagents storage. Development of ambient stable NAT reagents will go a long way towards alleviating these significant drawbacks. Traditionally, lyophilization has been the method of choice for drying NAT reagents such as Taq polymerase. However, lyophilization requires expensive specialized equipment & reagents, is time intensive, and is practically impossible to implement in a continuous mode operation. NeuMoDx has developed a simple, cost effective, high-throughput, and rapid drying procedure capable of producing highly

Claim	Claim Language	Infringement Evidence
		<p>effective NAT reagents using a conventional conveyer oven.</p> <ul style="list-style-type: none"> Three types of molecular diagnostic reagents were dried using unique formulations of select excipients: 1) Extraction reagents including magnetic particles with a nucleic acid affinity matrix, lytic enzymes, and encapsulated DNA/RNA process controls. 2) DNA PCR reagents, and 3) RT-PCR reagents. DNA/RNA isolation was performed in a variety of clinical matrices using the ambient stable reagents. At the end of the isolation step, the eluted nucleic acids were used directly to reconstitute dried PCR or RT-PCR mix and qPCR was performed. The efficacy of these dried reagents was evaluated by both DNA and RNA assays, such as NeuMoDx HBV and HCV assays to assess critical analytical performance metrics such as limit of detection, linearity, quantification etc. Accelerated aging studies were also performed with all three dried reagent formulations to assess the long-term stability of these reagents. <p style="text-align: center;">DRYING PROCESS</p>  <p style="text-align: center;">NeuMoDx-CVS-DryReagent_Poster-FNL.HD .pdf (Exhibit 81)</p>

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • Reagents used for molecular diagnostics are typically stored frozen or at least refrigerated to maintain viability. The proprietary NeuDry process developed by NeuMoDx offers a simple, low cost, and rapid process using a conventional conveyer oven to produce ready to use, ambient condition stable reagents capable of providing long open-shelf life for active reagents used in molecular diagnostic testing. The performance of reagents produced using the NeuDry process across wide variety of molecular diagnostic applications is presented here. • Three types of reagents formulated and optimized for both long term storage and in-use shelf life were produced using the NeuDry process - 1) Nucleic acid isolation reagents including NeuMag™ affinity particles, lytic enzyme, and encapsulated DNA/RNA process controls, 2) PCR Master mix, and 3) RT-PCR Master mix. Performance of the NeuDry reagents was initially evaluated against the liquid version of these reagents. Efficacy of the reagents was further evaluated by testing across a variety of clinical matrices encompassing both DNA and RNA targets. Long-term stability and in-use shelf life was determined via accelerated and real time stability studies on fully automated NeuMoDx Molecular System.

Claim	Claim Language	Infringement Evidence
		<p style="text-align: center;">DRYING PROCESS</p> <div style="text-align: center;">  <p>PCR OR RT-PCR FORMULATION NUCLEIC ACID EXTRACTION FORMULATION</p> <p>DISPENSE</p> <p>DRY, 15-20 MIN</p> <p>PACKAGE</p> </div> <p>40600293-SDS-201500-vA-EBV-quant.pdf (Exhibit 77)</p> <ul style="list-style-type: none"> The NeuMoDx EBV Quant Test Strip is a final finished product that contains reagents required to perform the human Epstein-Barr virus (EBV) test on the NeuMoDx Molecular System. Each test strip contains dried reagents in 16 individual wells and is sealed with a pierceable foil top. The final

Claim	Claim Language	Infringement Evidence
		<p>dried reagent solution is light pink. Exemptions for disclosing some component information are pursuant to CLP Article 1(5)(d) and 29 CFR 1910. 1200(g)(2)(i)(C)(1)&(2).</p> <p>40600230-SDS-201400-vB-CMVquant.pdf (Exhibit 79)</p> <ul style="list-style-type: none"> The NeuMoDx CMV Quant Test Strip is a final finished product that contains reagents required to perform the human Cytomegalovirus (CMV) test on the NeuMoDx Molecular System. Each test strip contains dried reagents in 16 individual wells and is sealed with a pierceable foil top. The final dried reagent solution is light pink. Exemptions for disclosing some component information are pursuant to CLP Article 1(5)(d) and 29 CFR 1910. 1200(g)(2)(i)(C)(1)&(2). <p>40600172_Rev-B-SDS-LDT-MM-RNA-Final-1.pdf (Exhibit 73)</p> <ul style="list-style-type: none"> The LDT Master Mix Test Strip, RNA (LDT MM, RNA) is a final finished product that contains reagents required to perform the Laboratory Developed Tests (LDT) on the NeuMoDx Molecular System for <i>in vitro</i> diagnosis only. Each test strip contains dried reagents in 16 individual wells and is sealed with a pierceable foil top. The final dried reagent is light pink. Exemptions for disclosing some component information are pursuant to CLP Article 1(5)(d) and 29 CFR 1910. 1200(g)(2)(i)(C)(1)&(2). <p>40600171_Rev-B-SDS-LDT-MM-DNA-FINAL.pdf (Exhibit 74)</p> <ul style="list-style-type: none"> The LDT Master Mix Test Strip, DNA (LDT MM, DNA) is a final finished product that contains reagents required to perform Laboratory Developed Tests (LDT) on the NeuMoDx Molecular System for in vitro diagnosis only. Each test strip contains dried reagents in 16 individual wells and is sealed with a pierceable foil top. The final dried reagent is light pink. Exemptions for disclosing some component information are pursuant to CLP Article 1(5)(d) and 29 CFR 1910. 1200(g)(2)(i)(C)(1)&(2). <p>40600170_Rev-C-SDS-NeuMoDx-CTNG-Test-Strip-200300-FINAL-08Mar2019 (Exhibit 75)</p> <ul style="list-style-type: none"> The CTNG Test Strip is a final finished product that contains reagents required to perform the NeuMoDx CTNG test on the NeuMoDx Molecular System for in vitro diagnosis only. Each test strip contains dried reagents in 16 individual wells and is sealed with a foil top. The final dried reagent is pink/purple. Exemptions for disclosing some component information are pursuant to CLP Article 1(5)(d) and 29 CFR 1910. 1200(g)(2)(i)(C)(1)&(2).

Claim	Claim Language	Infringement Evidence
		<p>40600111_Rev-B-SDS-NeuMoDx-GBS-Test-Stip-DRAFT-14Mar2019.pdf (Exhibit 76)</p> <ul style="list-style-type: none"> The SDS for the GBS Test strip is for the final finished product for use in the laboratory. The Test Strip contains dried reagents stored in 16 individual wells per Test Strip and sealed with foil. The final dried reagent solution is pink/purple. Exemptions for disclosing some component information are pursuant to CLP Article 1(5)(d) and 29 CFR 1910. 1200(g)(2)(i)(C)(1)&(2). <p>40600145_-Rev-D-IFU-NeuMoD-LDT-Master-Mix-DNA-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 67)</p> <ul style="list-style-type: none"> The NeuMoDx™ LDT Master Mix Test Strip, DNA (NeuMoDx™ LDT MM Test Strip, DNA) is a 16-well strip that contains a proprietary, room temperature stable, real-time PCR master mix reagent that when used in conjunction with assay specific primers and probe(s) enables a laboratory to rapidly develop and implement laboratory developed tests (LDTs) on the NeuMoDx™ 288 and NeuMoDx™ 96 Molecular System (NeuMoDx™ System(s)). Other than the LDT specific primers and probe(s), the NeuMoDx LDT MM Test Strip, DNA incorporates all the reagents required for real-time PCR. Once validated by the user's laboratory as part of the LDT, this reagent can be used as a key component for rapid automation of the LDT. Laboratory developed tests incorporating the NeuMoDx LDT MM Test Strip, DNA and implemented on the NeuMoDx System offer clinical laboratories a simple, efficient, and straightforward way to rapidly integrate LDTs for sample to result operation. The NeuMoDx System incorporates extraction, purification, quantification, and results interpretation. The System provides the opportunity to combine a universal nucleic acid isolation process with the use of the NeuMoDx LDT MM Test Strip, DNA and general-purpose real-time PCR reagents, to deliver highly accurate results for LDTs from unprocessed clinical samples. The user simply provides assay specific primers and probe(s) on a separate empty NeuMoDx™ LDT Test Strip [REF 100400] and defines the desired real-time PCR thermal profile. Once the clinical specimens and assay-specific reagents are properly loaded on the NeuMoDx System, the System will automatically start processing the samples. Upon lysis, the released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound DNA is eluted using NeuMoDx™ RELEASE Solution. The NeuMoDx System mixes the released DNA with the user provided LDT primers and probe(s) and then uses an aliquot of this solution to rehydrate the dried assay reagents in the NeuMoDx LDT MM Test Strip, DNA, which

Claim	Claim Language	Infringement Evidence
		<p>contains all the reagents necessary to perform a real-time PCR- specifically Taq DNA polymerase, dNTPS, MgCl2 and other optimized excipients and buffering agents. These dried assay reagents also contain the components required to amplify a section of the Sample Process Control 1 (SPC1) sequence to enable simultaneous amplification and detection of both target and control DNA sequences. The dried assay reagents in the NeuMoDx LDT MM Test Strip, DNA do not contain any LDT specific primers or probes (assay specific reagents) other than the SPC1 primers and probe; the assay specific reagents must be added by the user to the NeuMoDx LDT Test Strip. Upon mixing with the user-provided primers & probe(s) and reconstitution of the dried PCR reagents, the NeuMoDx System dispenses the prepared real-time-PCR-ready mixture into the NeuMoDx Cartridge. Amplification and detection of the control and target (if present) DNA sequences occur in the PCR chamber of the cartridge. The chamber and the cartridge are designed to contain the amplicon following real-time-PCR and essentially eliminate contamination risk post-amplification.</p> <p>40600106_Rev-D-IFU-NeuMoDx-Lysis-Buffer-1-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 63)</p> <ul style="list-style-type: none"> • The NeuMoDx Systems mix the released nucleic acid with assay specific primers and probe(s) as well as the dried Master Mix contained in a NeuMoDx™ test strip. The system then dispenses the prepared PCR-ready mixture into the NeuMoDx Cartridge where Real-Time PCR occurs. <p>40600105_Rev-D-IFU-NeuMoDx-Lysis-Buffer-2-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 64)</p> <ul style="list-style-type: none"> • The NeuMoDx Systems mix the released nucleic acid with assay specific primers and probe(s) as well as the dried Master Mix contained in a NeuMoDx™ test strip. The system then dispenses the prepared PCR-ready mixture into the NeuMoDx Cartridge where Real-Time PCR occurs. <p>40600104_Rev-D-IFU-NeuMoDx-Lysis-Buffer-3-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 65)</p> <ul style="list-style-type: none"> • The NeuMoDx Systems mix the released nucleic acid with assay specific primers and probe(s) as well as the dried Master Mix contained in a NeuMoDx™ test strip. The system then dispenses the prepared PCR-ready mixture into the NeuMoDx Cartridge where Real-Time PCR occurs. <p>40600103_Rev-D-IFU-NeuMoDx-Lysis-Buffer-4-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 66)</p> <ul style="list-style-type: none"> • The NeuMoDx Systems mix the released nucleic acid with assay specific primers and probe(s) as well as the dried Master Mix contained in a NeuMoDx™ test strip. The system then dispenses the prepared PCR-ready mixture into the NeuMoDx Cartridge where Real-Time PCR occurs.

Claim	Claim Language	Infringement Evidence
		<p>40600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 20)</p> <ul style="list-style-type: none"> The NeuMoDx Systems mix the released nucleic acid with assay specific primers and probe(s) and the dried Master Mix contained in a NeuMoDx test strip. The System then dispenses the prepared RT-PCR-ready mixture into the NeuMoDx Cartridge where Real-Time PCR occurs. <p>40600100_Rev-D-IFU-NeuMoDx-WASH-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 58)</p> <ul style="list-style-type: none"> The NeuMoDx Systems mix the released nucleic acid with assay specific primers and probe(s) as well as the dried Master Mix contained in a NeuMoDx™ test strip. The system then dispenses the prepared PCR-ready mixture into the NeuMoDx Cartridge where Real-Time PCR occurs. <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> The NeuMoDx Systems mix the released nucleic acid with assay specific primers and probe(s) as well as the dried Master Mix contained in a NeuMoDx test strip. The system then dispenses the prepared PCR-ready mixture into the NeuMoDx Cartridge where Real-Time PCR occurs. <p>40600129_D-IFU-GBS-Strip_US-only (Exhibit 60)</p> <ul style="list-style-type: none"> “The NeuMoDx System uses a combination of heat, lytic enzyme and extraction reagents to perform cell lysis, DNA extraction and removal of inhibitors. The released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are loaded into the NeuMoDx™ Cartridge where the unbound, non-DNA components are further washed away with NeuMoDx™ WASH Solution and the bound DNA is eluted using NeuMoDx™ RELEASE Solution. The NeuMoDx System then uses the released DNA to rehydrate dried assay reagents containing all the elements necessary for amplification of the GBS-specific target. The dried PCR reagents also contain the components required to amplify a section of the Sample Process Control sequence to enable simultaneous amplification and detection of both target and control DNA sequences. After reconstitution of the dried PCR reagents, the NeuMoDx System dispenses the prepared PCR-ready mixture into one PCR chamber (per specimen) of the NeuMoDx Cartridge. Amplification and detection of the control and target (if present) DNA sequences occur in PCR chamber. The chamber and the cartridge are designed to contain the amplicon following real-time-PCR and essentially eliminate contamination risk post-amplification..” <i>Id.</i> at 1. “NeuMoDx™ GBS Test Strip: Dried PCR reagents containing GBS-specific TaqMan® probe

Claim	Claim Language	Infringement Evidence
		<p>and primers along with Sample Process Control-specific TaqMan® probe and primers.” <i>Id.</i> at 2.</p> <p>40600147_D-IFU-NeuMoDx-LDT-Test-Strip-US-ONLY (Exhibit 61)</p> <ul style="list-style-type: none"> • “The NeuMoDx™ LDT Test Strip is an empty 16-well strip which is utilized for laboratory developed tests (LDTs) on the NeuMoDx™ 288 NeuMoDx™ and 96 Molecular System (NeuMoDx™ System(s)). NeuMoDx Systems in conjunction with other NeuMoDx™ reagents such as NeuMoDx™ Extraction Plate, NeuMoDx™ lysis buffers, NeuMoDx™ WASH Solution and the NeuMoDx™ RELEASE Solution makes the development of LDTs streamlined and efficient as it combines sample extraction with Real Time PCR in one system. The NeuMoDx LDT Test Strip is universally used for all LDTs processed on either NeuMoDx System.” <i>Id.</i> at 1. • “The NeuMoDx LDT Test Strip is a foil-covered, empty, 16-well disposable plastic strip into which the user pipets assay-specific primers and probe(s) to process LDTs on a NeuMoDx System. It is used in parallel with NeuMoDx™ LDT Master Mix Test Strip, DNA or RNA which contain the required elements for real-time PCR including the Taq DNA polymerase, Reverse Transcriptase (if required), dNTPs, MgCl2 and other buffer components.” <i>Id.</i> • “The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using the NeuMoDx RELEASE Solution. The NeuMoDx System mixes the released nucleic acid with the user provided LDT primers and probe(s) in the NeuMoDx LDT Test Strip and then uses an aliquot of this solution to rehydrate the dried assay reagents in the appropriate NeuMoDx LDT Master Mix Test Strip (DNA or RNA). Upon mixing with the user-provided primers & probe(s) (LDT-specific reagents) and reconstitution of the dried PCR reagents, the NeuMoDx System will dispense the prepared PCR-ready mixture into the NeuMoDx Cartridge where Real-Time PCR occurs.” <i>Id.</i> <p>40600146_D-IFU-NeuMoDx-LDT-Master-Mix-RNA-US-ONLY (Exhibit 62)</p> <ul style="list-style-type: none"> • “The NeuMoDx™ LDT Master Mix Test Strip, RNA (NeuMoDx™ LDT MM Test Strip, RNA) is a 16-well strip that contains a proprietary, room temperature stable, real-time PCR master mix reagent that when used in conjunction with assay specific primers and probe(s) enables a laboratory to rapidly develop and implement laboratory developed tests (LDTs) on the NeuMoDx™ 288 and NeuMoDx™ 96 Molecular System (NeuMoDx™ System(s)). Other than the LDT specific primers and

Claim	Claim Language	Infringement Evidence
		<p>probe(s), the NeuMoDx LDT MM Test Strip, RNA incorporates all the reagents required for real-time RT-PCR. Once validated by the user's laboratory as part of the LDT, this reagent can be used as a key component for rapid automation of the LDT." <i>Id.</i> at 1.</p> <ul style="list-style-type: none"> • "Laboratory developed tests incorporating the NeuMoDx LDT MM Test Strip, RNA and implemented on the NeuMoDx System offer clinical laboratories a simple, efficient, and straightforward way to rapidly integrate LDTs for sample to result operation. The NeuMoDx System incorporates extraction, purification, quantification and results interpretation. The System provides the opportunity to combine a universal nucleic acid isolation process with the NeuMoDx LDT MM Test Strip, RNA and general real-time, reverse transcription (RT) - PCR reagents, delivering highly accurate results for LDTs from unprocessed clinical samples. The user simply provides assay specific primers and probe(s) on a separate empty NeuMoDx™ LDT Test Strip [REF 100400] and defines the desired real-time, RT-PCR thermal profile. Once the clinical specimens and assay-specific reagents are loaded on the NeuMoDx System, the System automatically starts processing the samples." <i>Id.</i> • "The NeuMoDx Systems use a combination of heat, lytic enzymes, and extraction reagents to perform cell lysis, RNA extraction and removal of inhibitors from unprocessed clinical specimens prior to presenting the extracted RNA for detection by real-time RT-PCR. Upon lysis, the released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound RNA is eluted using NeuMoDx™ RELEASE Solution. The NeuMoDx System mixes the released RNA with the user provided LDT primers and probe(s) and then uses an aliquot of this solution to rehydrate the dried RT-PCR reagents in the NeuMoDx LDT MM Test Strip, RNA, which contains all the reagents necessary to perform a one-step real-time RT-PCR reaction - specifically Reverse Transcriptase, Taq DNA polymerase, dNTPS, MgCl2 and other optimized excipients and buffering agents as well as the primers and probe specific for the Sample Process Control 2 (SPC2) sequence to enable simultaneous amplification and detection of both target and control RNA sequences. The dried RT-PCR reagents in the NeuMoDx LDT MM Test Strip, RNA do not contain any LDT specific primers or probes (assay specific reagents) other than the SPC2 primers and probe; the assay specific reagents must be added by the user to the NeuMoDx LDT Test Strip. Upon mixing with the user-provided primers & probe(s) and reconstitution of the dried RT-PCR reagents the NeuMoDx System dispenses the prepared RT-PCR-ready mixture into the NeuMoDx Cartridge. Amplification and detection of the control and target (if present) RNA sequences occur in

Claim	Claim Language	Infringement Evidence
		<p>the PCR chamber of the cartridge. The chamber and the cartridge are designed to contain the amplicon following RT-PCR and virtually eliminate contamination risk post-amplification.” <i>Id.</i> at 2.</p> <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> Patent No. 9,382,532 at 25:51-26:10 (“Thereafter in the first illustration, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 10. The system of claim 1, further comprising an assay strip comprising at least one reagent well, each containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume. Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample,

Claim	Claim Language	Infringement Evidence
		<p>and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 24. The system of claim 23, further comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample, a lysing reagent, and a sample process control, wherein the capture plate facilitates production of at least one biological sample combined with magnetic beads; an assay strip comprising at least one reagent well containing molecular diagnostic reagent volume configured to be combined with a nucleic acid volume of the set of nucleic acid volumes to produce at least one nucleic acid-reagent mixture; and a liquid handling system configured to transfer at least one biological sample combined with magnetic beads from the capture plate to the molecular diagnostic module, transfer at least one nucleic acid-reagent mixture from the assay strip back to the molecular diagnostic module • U.S. Patent No. 9,050,594 at col. 2:49-58 (“As shown in FIGS. 1A-1B and 7A, an embodiment of a system 100 for processing and detecting nucleic acids comprises: a capture plate 110 configured to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119; a molecular diagnostic module 130 comprising a microfluidic cartridge receiving the module 140, heating and cooling subsystems 150, a magnet 160, a valve actuation sub-system 170, an optical subsystem 180; and an assay strip configured to facilitate mixing of molecular diagnostic reagents with a nucleic acid volume.”) • U.S. Patent No. 9,050,594 at 3:33-46 (“The liquid handling system 250 then aspirates the set of nucleic acids from the microfluidic cartridge 210 contained within the molecular diagnostic module 130, combines the set of nucleic acids with a set of molecular diagnostic reagents using an assay strip 190, and dispenses the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the microfluidic cartridge 210 within the molecular diagnostic module 130. The detection chamber heaters 157, optical subsystem 180 and valve actuation subsystem 170 of the molecular diagnostic module 130 then facilitate analysis of the set of nucleic acid-reagent mixtures by a processor configured to display information on a user interface.”)


Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at col. 19:45-51 (“As shown in FIGS. 18A and 18B, the assay strip 190 comprises an assay strip substrate 191 comprising a set of wells 192, and typically a puncturable foil seal 195, and functions to facilitate combination of a set of nucleic acid samples with a set of molecular diagnostic reagents for amplification and/or detection of a nucleic acid sequence or sequences.”) U.S. Patent No. 9,050,594 at col. 21:7-15 (“one variation, the assay strip 190 may be prepackaged with a set of molecular diagnostic reagents, such that each well 193 in the set of wells 192 is prepackaged with a quantity of molecular diagnostic reagents. The set of wells 192 may then be sealed by the puncturable foil seal 195, which is configured to be punctured by an external element that delivers volumes of nucleic acid samples to be combined with the set of molecular diagnostic reagents.”) <p>US9441219 (Exhibit 53)</p> <ul style="list-style-type: none"> Claim 7. The molecular diagnostic module of claim 1, further comprising: a capture plate comprising a well containing a set of magnetic beads, a lysing reagent, and a sample process control, configured to be combined with the biological sample, wherein the capture plate facilitates production of a magnetic bead-sample from the biological sample and the set of magnetic beads; an assay strip comprising a reagent well containing a molecular diagnostic reagent volume configured to be combined with the nucleic acid volume processed from the magnetic-bead sample, thereby generating a nucleic acid-reagent mixture; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the cartridge, transfer the nucleic acid volume from the cartridge to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip back to the cartridge. U.S. Patent No. 9,441,219 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”)

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • U.S. Patent No. 9,441,219 at col. 20:9-15 (“A shown in FIGS. 18A and 18B, the assay strip 190 comprises an assay strip substrate 191 comprising a set of wells 192, and typically a puncturable foil seal 195, and functions to facilitate combination of a set of nucleic acid samples with a set of molecular diagnostic reagents for amplification and/or detection of a nucleic acid sequence or sequences.”) • U.S. Patent No. 9,441,219 at col. 31:9-26 (“Step S450 recites combining each nucleic acid volume of the set of nucleic acid volumes with a molecular diagnostic reagent of a set of molecular diagnostic reagents to produce a set of nucleic acid-reagent mixtures, which functions to prepare the set of nucleic acid volumes to be detected. For each nucleic acid volume in the set of nucleic acid volumes, Step S450 preferably comprises aspirating an entire volume of the nucleic acid volume from its corresponding fluidic pathway, and transferring the nucleic acid volume to a well containing a molecular diagnostic reagent.”) • US 9,441,219 col. 32:3-14 (“In a specific example of Step S450, a multichannel liquid handling system aspirates approximately 18 μL of each of a set of nucleic acid volumes from the microfluidic cartridge used in the specific example of Step S440 using a set of pipette tips, punctures at least one foil seal 195 of at least one assay strip, wherein each well of the at least one assay strip contains molecular diagnostic reagents, and dispenses each aspirated nucleic acid volume into a well of the assay strip. In the specific example of the S450, the multichannel liquid handling system then aspirates and dispenses the contents of each well approximately 10 times to reconstitute molecular diagnostic reagents and mix the contents of each well.”)

EXHIBIT 90

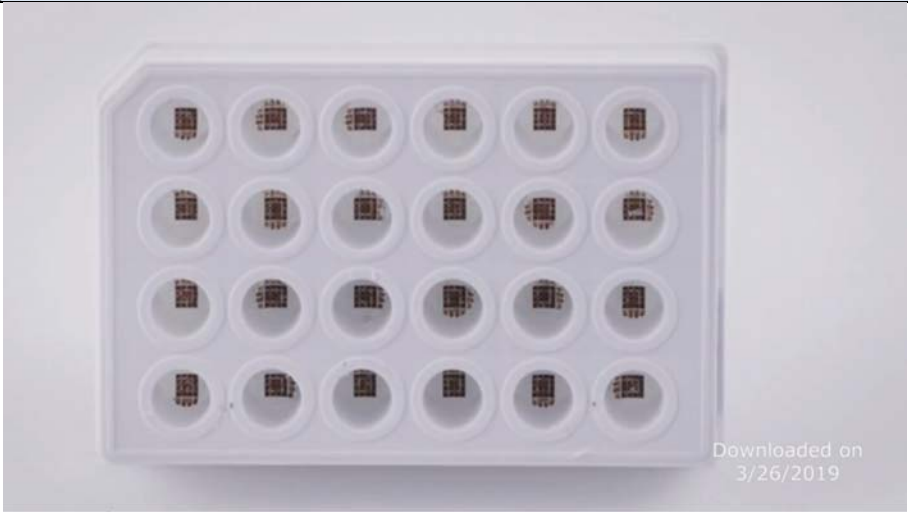
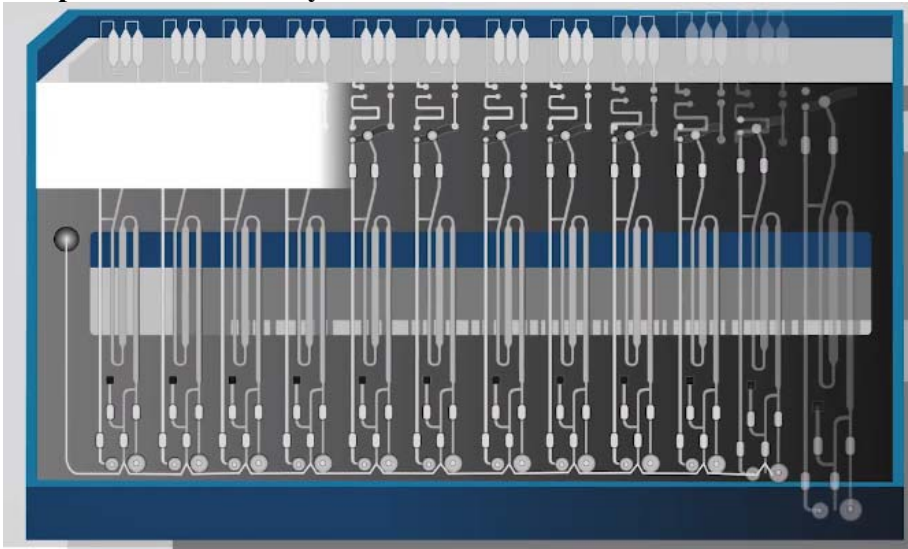
Exhibit 90

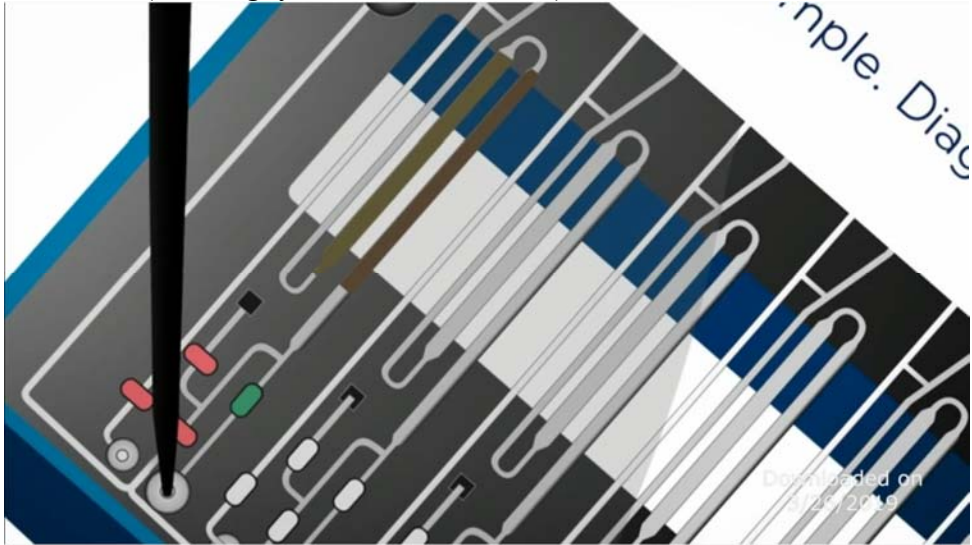
U.S. Patent No. 10,625,261 Infringement Chart


Claim	Claim Language	Infringement Evidence
1(a)	A system for processing a plurality of nucleic acid-containing samples, the system comprising:	<p>To the extent that the preamble is limiting, the accused system is for processing a plurality of nucleic acid-containing samples.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-products/, last visited June 5, 2019 (Exhibit 12)</p>  <p>#500200 NeuMoDx™ 96 Molecular System</p> <p>#500100 NeuMoDx™ 288 Molecular System</p>

Claim	Claim Language	Infringement Evidence
		<p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul style="list-style-type: none"> • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result.” <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> • “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieveing [sic] optimal operational and clinical performance for our customers and their patients.” • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents. • “The NeuMoDx™ 96 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 288 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated

Claim	Claim Language	Infringement Evidence
		<p>amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 288 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.”</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/dr-steven-young-video-testimonial/, hyperlink at https://youtu.be/vukP6gbLBYE. (Exhibit 32)</p> <ul style="list-style-type: none"> At 2:58-3:18 (“There’s two systems that have been put into operation by NeuMoDx. One is the 288. It’s a high-throughput instrument, versus the 96, which is a lower throughput instrument. The advantage is that both systems use all of the same chemistry and all of the same hardware. Its just a smaller footprint.”)
1(b)	a first module configured to extract nucleic acids from the plurality of nucleic acid-containing samples,	<p>The accused system comprises a first module configured to extract nucleic acids from the plurality of nucleic acid-containing samples.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “Liquid Handling Processing A: Lysis and Capture. Dispensing lysis buffer. Dispensing lysis buffer and patient specimen into extraction plate. The liquid handling robot delivers lysis buffer and patient specimen to the extraction plate, which has 24 independent wells which contain NeuDry affinity-coated paramagnetic beads. Each mixture is aspirated and dispensed five times to ensure homogeneity of the solution. During the transfer of patient specimen to the extraction plate the liquid handling robot uses pre-defined no-fly zones to reduce the potential of contamination.” <i>Id.</i> at 0:28-1:05 <i>Id.</i> at 0:40 (showing the extraction plate).

Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none"> • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59 

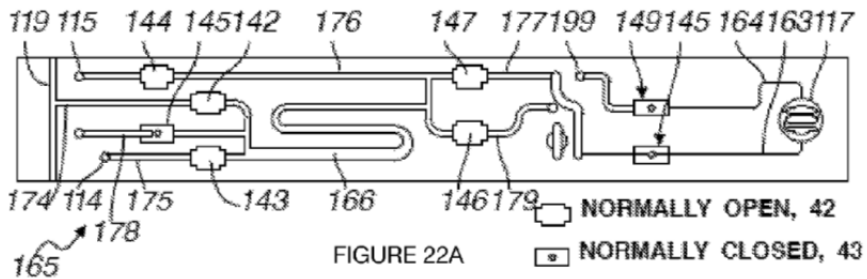
Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” <i>Id.</i> at 2:28-2:39. • <i>Id.</i> at 2:28 (showing lysate in the s-channel).  <ul style="list-style-type: none"> • “A precise volume of air is then applied to remove any remaining liquid into the waste chamber. NeuMoDx wash solution is pumped via the fluid port into the microfluidic cartridge to remove all unbound material, followed by another volume of air to remove excess wash solution. High pH NeuMoDx release reagent is dispensed into the s-channel to cover the beads, and heat is applied to the denaturation process, resulting in released nucleic acid or eluate.” <i>Id.</i> at 2:39-3:12. • <i>Id.</i> at 2:43-3:00 (showing dispensing of the wash solution and release solution

Claim	Claim Language	Infringement Evidence										
		<div></div> <p>“Patents”, http://www.neumodx.com/patents/, (Exhibit 47) demonstrating that NeuMoDx marks its products with US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; 9,452,430; 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; 10,010,888; 9,382,532; 9,540,636; 9,499,896; 10,239,060; 9,539,576; 10,226,771, 9,637,775; and 10,093,963</p> <h2>PATENTS</h2> <table><tr><th>Product</th><th>Patents</th></tr><tr><td>CARTRIDGE</td><td>US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.</td></tr><tr><td>P02 (overall system and method)</td><td>US Patent Nos. 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; and 10,010,888. CN Patent No. 201380009286.3.</td></tr><tr><td>EXTRACTION PLATE</td><td>US Patent Nos. 9,382,532; and 9,540,636. DE Patent No. 60 2013 056 932.0. DK Patent No. 2912174. EP Patent No. EP-B-2912174. ES Patent No. 300330453. FR Patent No. 2912174. GB Patent No. 2912174. IT Patent No. 502019000064944. NO Patent No. 2912174. SE Patent No. 2912174.</td></tr><tr><td>XPCR MODULE</td><td>US Patent Nos. 9,499,896; 10,239,060; 9,539,576; 10,226,771; 9,637,775; 10,093,963; 9,604,213; and 10,010,888.</td></tr></table> <p>US9382532 (Exhibit 52)</p>	Product	Patents	CARTRIDGE	US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.	P02 (overall system and method)	US Patent Nos. 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; and 10,010,888. CN Patent No. 201380009286.3.	EXTRACTION PLATE	US Patent Nos. 9,382,532; and 9,540,636. DE Patent No. 60 2013 056 932.0. DK Patent No. 2912174. EP Patent No. EP-B-2912174. ES Patent No. 300330453. FR Patent No. 2912174. GB Patent No. 2912174. IT Patent No. 502019000064944. NO Patent No. 2912174. SE Patent No. 2912174.	XPCR MODULE	US Patent Nos. 9,499,896; 10,239,060; 9,539,576; 10,226,771; 9,637,775; 10,093,963; 9,604,213; and 10,010,888.
Product	Patents											
CARTRIDGE	US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.											
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EXTRACTION PLATE	US Patent Nos. 9,382,532; and 9,540,636. DE Patent No. 60 2013 056 932.0. DK Patent No. 2912174. EP Patent No. EP-B-2912174. ES Patent No. 300330453. FR Patent No. 2912174. GB Patent No. 2912174. IT Patent No. 502019000064944. NO Patent No. 2912174. SE Patent No. 2912174.											
XPCR MODULE	US Patent Nos. 9,499,896; 10,239,060; 9,539,576; 10,226,771; 9,637,775; 10,093,963; 9,604,213; and 10,010,888.											

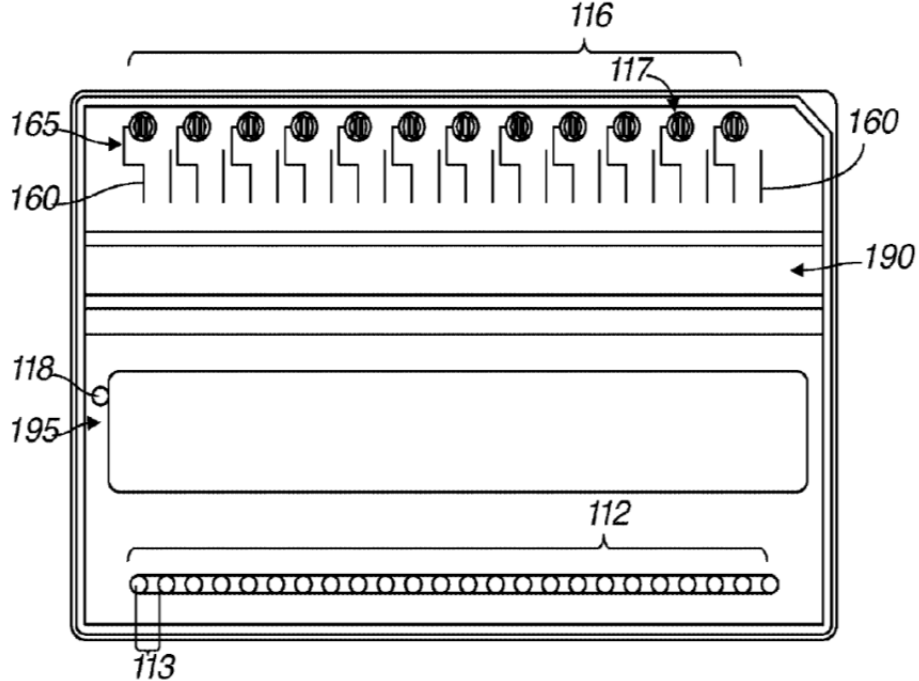
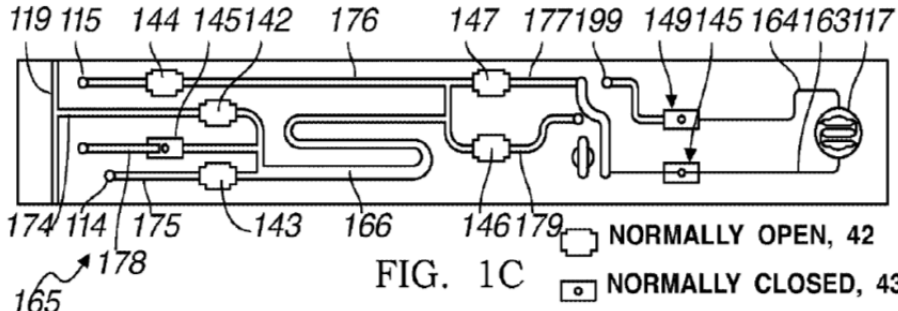
Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10. Clam 10. The method of claim 3, wherein washing the set of moiety-bound nucleic acid particles comprises aspirating the moiety-sample mixture; receiving the cartridge at the cartridge receiving module comprising the set of pins and a cam card interfacing with the set of pins; transitioning the cartridge to an active configuration that disposes the cartridge proximal the set of pins; displacing the first subset of the set of pins in the active configuration of the cartridge, upon translation of the cam card relative to the set of pins, thereby occluding the fluidic pathway of the cartridge at a set of occlusion positions; delivering the moiety-sample mixture into the fluidic pathway, wherein the fluidic pathway is configured to pass through a magnetic field

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		<p>and is coupled to a waste chamber, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field; and delivering a wash solution through the fluidic pathway and into the waste chamber in a continuous flow operation.</p> <ul style="list-style-type: none"> • Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second subset of the set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction. • Claim 19. A method for nucleic acid isolation from a biological sample, comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution includes a set of affinity moiety-coated microparticles, comprising a set of microparticles amide-bonded to at least one of Poly(allylamine) of molecular weight <30,000 Da and Polypropylenimine

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		<p>tetramine dendrimer Generation 1; producing a moiety-sample mixture upon combination of the binding moiety solution with the biological sample; producing a set of moiety-bound nucleic acid particles upon incubation of the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of the set of pins includes reversing displacement of at least one pin of the first subset of the set of pins, and reversing occlusion of a portion of the fluidic pathway.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at Abstract (“A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber; mixing the binding moiety solution with a biological sample, within the process chamber, in order to produce a moiety-sample mixture; incubating the moiety-sample mixture during a time window, thereby producing a solution comprising a set of moiety-bound nucleic acid particles and a waste volume; separating the set of moiety-bound nucleic acid particles from the waste volume; washing the set of moiety-bound nucleic acid particles; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles.”) • U.S. Patent No. 9,382,532 at 7:14-19 (“In Step S140, the lysed moiety-sample solution can be processed within the process chamber to separate the moiety-bound nucleic acid volume from the waste volume; however, the lysed moiety-sample solution can alternatively be transferred to another suitable vessel for separation of the moiety-bound nucleic acid volume from the waste volume.”)

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		<ul style="list-style-type: none"> U.S. Patent No. 9,382,532 at 24:1-14 “A first illustration of the eighteenth example, as shown in FIG. 22A, of a fluidic pathway 165 preferably comprises an initial segment 174 fluidically coupled to a fluid channel 119 coupled to a shared fluid port 118, a sample segment 175 coupled to a sample port 114 and to the initial segment 174, and an s-shaped capture segment 166, configured to pass through the heating region 195 and a magnetic field 156, coupled to the initial segment 174 and the sample segment 175. In an alternative illustration of the eighteenth example, 10 the s-shaped capture segment 166 may comprise an initial wide arc 166 to provide a greater surface area for magnetic bead capture. In another illustration of the eighteenth example, the capture segment 166 may alternatively be a progressively narrowing s-shaped capture segment 166.”) U.S. Patent No. 9,382,532 at FIG. 22A:  <p>FIGURE 22A</p> <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer,

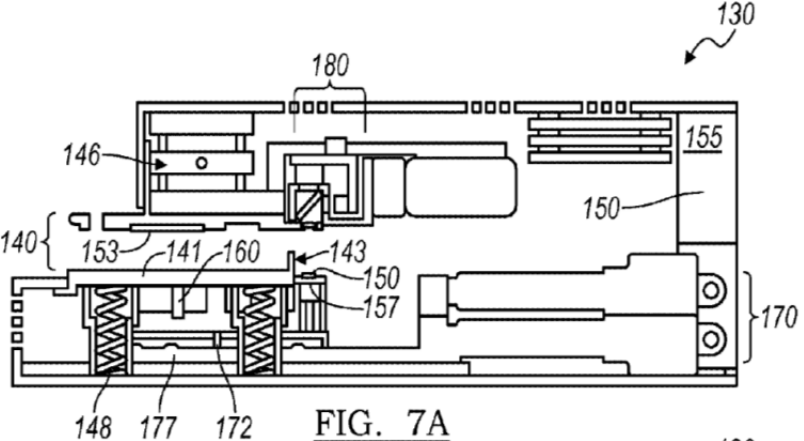
Claim	Claim Language	Infringement Evidence
		<p>wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position of the fluidic pathway, by way of the void of the corrugated surface, the fluidic pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber.</p> <ul style="list-style-type: none"> • Claim 4. The cartridge of claim 3, wherein the fluidic pathway comprises a capture segment, downstream of the sample port and configured to cross the magnet housing region multiple times. • U.S. Patent No. 9,403,165 at 3:27-32 (“As shown in FIGS. 1B and 1C, the top layer 110 preferably comprises a set of sample port-reagent port pairs 112, a fluid port 118, a vent region 190, a heating region 195 crossing a capture segment 166 of a fluidic pathway 165, and a set of detection chambers 116.”) • U.S. Patent No. 9,403,165 at 1A.

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		 <p style="text-align: center;">FIG. 1A</p> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at FIG. 1C .  <p style="text-align: center;">FIG. 1C</p> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at 3:32-43 (“Each sample-port-reagent port pair 113 of an embodiment of the top layer 110 comprises a sample port 114 and a

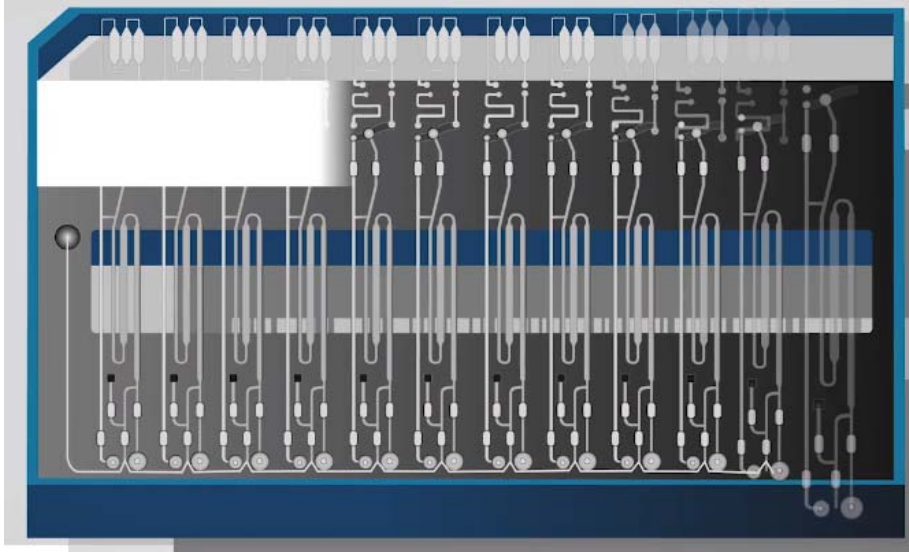
Claim	Claim Language	Infringement Evidence
		<p>reagent port 115. The sample port 114 functions to receive a volume of a sample fluid potentially containing the nucleic acids of interest for delivery of the volume of fluid to a portion of a fluidic pathway 165 coupled to the sample port-reagent port pair 113. In a specific embodiment, the volume of a sample fluid is a biological sample with magnetic beads for nucleic acid isolation; however, the volume of fluid comprising a sample fluid may alternatively be any appropriate fluid containing a sample with nucleic acids.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,403,165 at 3:53-67 (“Each sample-port reagent port pair 113 of an embodiment of the top layer 110 also comprises a reagent port 115, as shown in FIG. 1A. The reagent port 115 in a sample port-reagent port pair 113 functions to receive a volume of fluid comprising a reagent used in molecular diagnostics, for delivery of the volume of fluid comprising a reagent to a portion of a fluidic pathway 165 coupled to the sample port-reagent port pair 113. In a specific embodiment, the volume of fluid comprising a reagent used in molecular diagnostics is a sample of reconstituted molecular diagnostic reagents mixed with nucleic acids released and isolated using the microfluidic cartridge 100; however, the volume of fluid comprising a reagent used in molecular diagnostics may alternatively be any appropriate fluid comprising reagents used in molecular diagnostics.”) • U.S. Patent No. 9,403,165 at 14:39-50 (“As shown in FIGS. 1C, 6C, 7 and 9, a fluidic pathway 165 of the set of fluidic pathways 160 is branched and preferably comprises an initial segment 174 fluidically coupled to a fluid channel 119 coupled to a fluid port 118, a sample segment 175 coupled to a sample port 114, a reagent segment 176 coupled to a reagent port 115, a capture segment 166 passing through at least one of the heating region 195 and a magnetic field 156, a vent segment 177 configured to pass through the vent region 190, a segment running to a detection chamber 163, a segment running away from the detection chamber 164, and at least one waste segment 178, 179 configured to transfer a waste fluid to a waste chamber 130.”) • U.S. Patent No. 9,403,165 at 14:65-15:2 (“The capture segment 166 functions to facilitate isolation and purification of nucleic acids from the volume of the sample fluid, and may be s-shaped and/or progressively narrowing, to

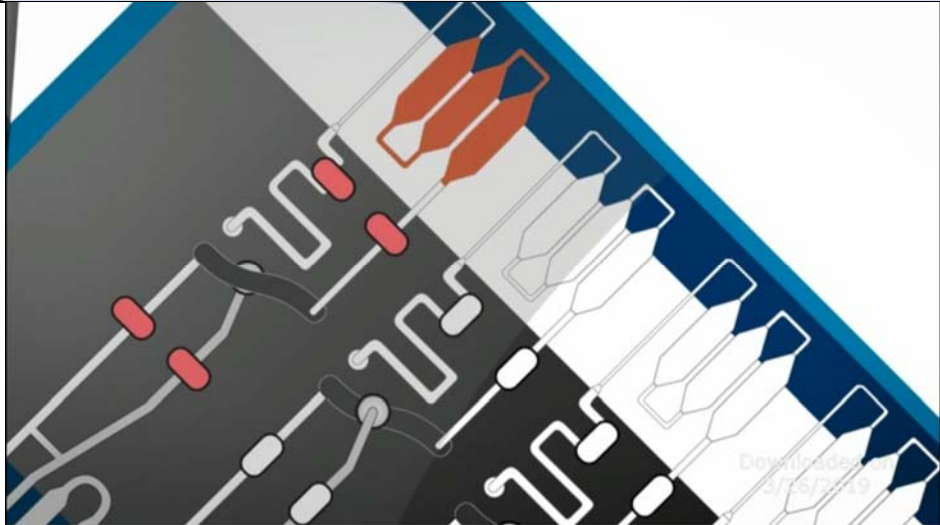
Claim	Claim Language	Infringement Evidence
		<p>increase the efficiency and/or effectiveness of isolation and purification.”)</p> <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer

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		<p>the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 23. A system for processing and detecting nucleic acids, comprising: a molecular diagnostic module, configured to process a set of biological samples combined with magnetic beads and separate a set of nucleic acid volumes from the set of biological samples combined with magnetic beads, wherein the molecular diagnostic module comprises an actuator configured to displace a cartridge, a set of pins, and at least one cam contacting the set of pins, wherein an extension or retraction of the actuator moves the cartridge, and a displacement of a subset of the set of pins defines a set of pathways in the cartridge, each configured to receive a biological sample combined with magnetic beads of the set of biological samples combined with magnetic beads. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) • U.S. Patent No. 9,050,594 at 3:1-6 (“The system 100 thus functions to receive biological samples containing nucleic acids (i.e., impure nucleic acid samples), separate nucleic acids from the biological samples, and analyze nucleic acid samples according to at least one molecular diagnostic protocol

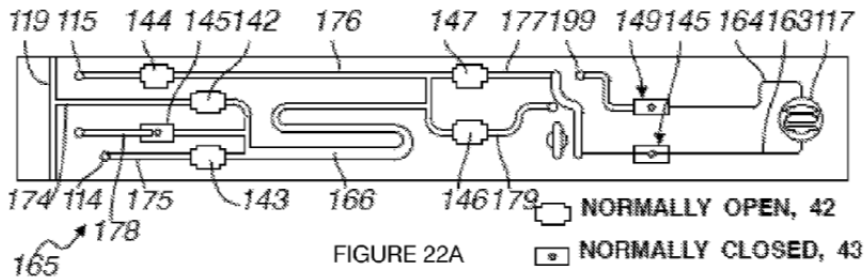
Claim	Claim Language	Infringement Evidence
		<p>(e.g., PCR).”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 2:3-5, FIG 7A (“FIGS. 7 A-7E depict a sequence of operations performed by elements of an embodiment of a molecular diagnostic module.”)  <p style="text-align: center;">FIG. 7A</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 22:29-33 (“The microfluidic cartridge 210 functions to receive a set of magnetic bead-samples, facilitate separation of nucleic acids from the set of magnetic bead-samples, receive a set of nucleic acid-reagent samples, and facilitate analysis of nucleic acids from the set of nucleic acid-reagent samples”) U.S. Patent No. 9,050,594 at 23:28-53 (“The liquid handling system 250 of the system 100 includes a liquid handling arm 255 and a syringe pump 265, as shown in FIGS. 14A-14C and functions to deliver biological samples, reagents, and gases to elements of the system 100. As described in Section 1, an embodiment of the liquid handling system 250 is configured to aspirate a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), dispense the set of biological samples into a capture plate no to be lysed and combined with magnetic beads by a capture plate module 120, aspirate the set of biological samples combined with magnetic beads (i.e., set of

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		<p>magnetic bead-samples) from the capture plate 110, and dispense the set of magnetic bead-samples into microfluidic cartridge 210 located in a molecular diagnostic module 130. The embodiment of the liquid handling system 100 is further configured to facilitate separation of a set of nucleic acids from the magnetic bead-samples, by dispensing a wash solution, a release solution, and/or air into the molecular diagnostic module 130, by the nozzle 149 coupled to the linear actuator 146, at appropriate stages, aspirate the set of nucleic acids from the molecular diagnostic module 130, combine the set of nucleic acids with a set of molecular diagnostic reagents using an assay strip 190, and dispense the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the molecular diagnostic module 130 for further processing and analysis.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 27:2-13 (“An embodiment of a method 400 for processing and detecting nucleic acids from a set of biological samples comprises: combining each biological sample of the set of biological samples with a quantity of magnetic beads to produce a set of magnetic bead-sample mixtures S410; heating the set of magnetic bead-sample mixtures to produce a set of nucleic acid-magnetic bead samples S420; transferring each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways S430; producing a set of nucleic acid volumes from the set of nucleic acid-magnetic bead samples S440”) • U.S. Patent No. 9,050,594 at 29:27-38 (“Step S440 recites producing a set of nucleic acid volumes from the set of nucleic acid-magnetic bead samples, and functions to separate nucleic acid volumes from the set of nucleic acid-magnetic bead samples. Step S440 preferably reduces a concentration of unwanted matter from the set of biological samples being processed, to an acceptable level; however, Step S440 may alternatively entirely remove substantially all unwanted substances from the set of biological samples being processed. Step S440 preferably includes providing a magnetic field S441, such that each fluidic pathway in the set of fluidic pathways is configured

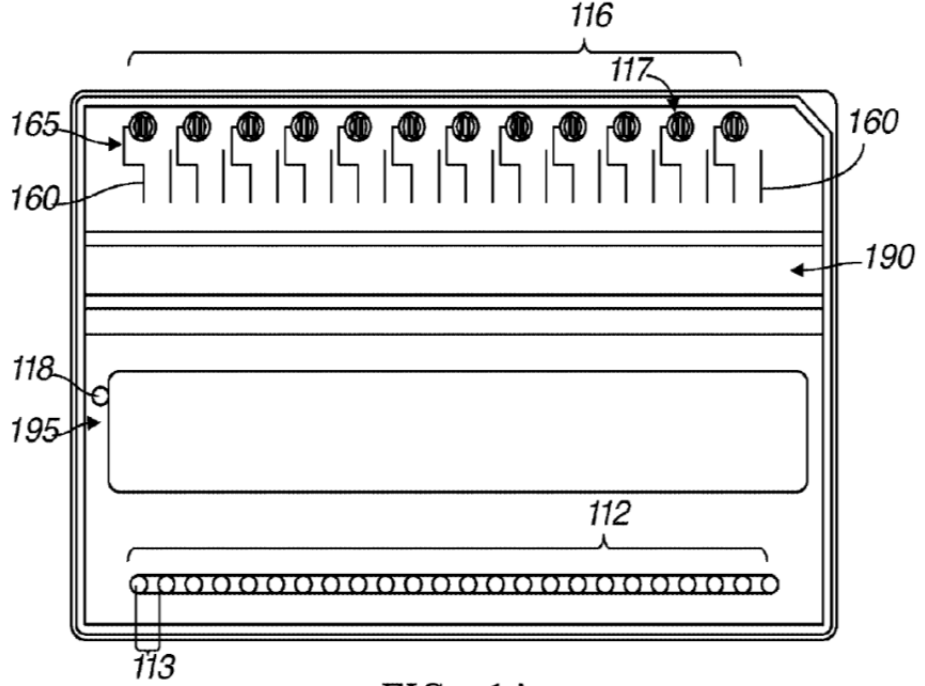
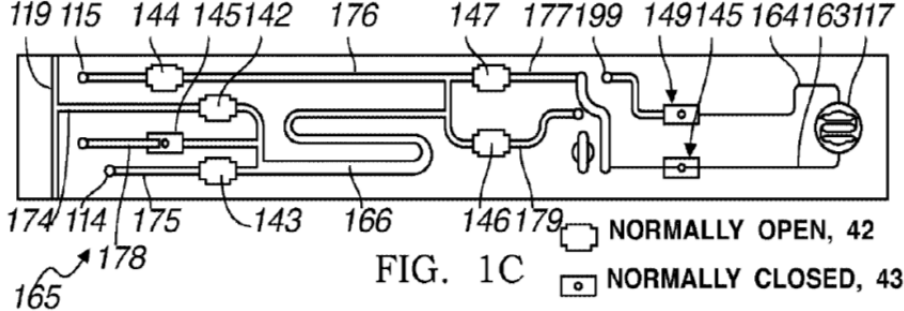
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		to cross the magnetic field.”)
1(c)	a second module configured to amplify the nucleic acid extracted from the plurality of nucleic acid-containing samples,	<p>The accused system comprises a second module configured to amplify the nucleic acid extracted from the plurality of nucleic acid-containing samples.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59  <ul style="list-style-type: none"> “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08 <i>Id.</i> at 4:08 (showing the three thin PCR chambers).

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		 <p data-bbox="804 829 1121 862">US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> <li data-bbox="852 870 1923 1409">Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing

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		<p>the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 16. The method of claim 1, further comprising processing the nucleic acid sample, wherein processing the nucleic acid sample comprises modulating the fluidic pathway of the cartridge upon displacement of a third subset of the set of pins, thereby defining a path to a diagnostic chamber of the cartridge, delivering the nucleic acid sample to the diagnostic chamber, and amplifying nucleic acids of the nucleic acid sample within the diagnostic chamber by polymerase chain reaction. • U.S. Patent No. 9,382,532 at 10:58-63. (“As shown in FIGS. 1A, 1B, and 2, the method 100 can further comprise Step S170, which recites processing the nucleic acid sample. Processing can comprise amplifying the nucleic acid(s) of the nucleic acid sample (e.g., by polymerase chain reaction), or any other suitable method for processing nucleic acids.”) • U.S. Patent No. 9,282, 532 at 26:7-10 (“An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”) • U.S. Patent No. 9,382,532 at FIG. 22A:

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		 <p data-bbox="1239 503 1375 527">FIGURE 22A</p> <p data-bbox="808 584 1123 617">US9403165 (Exhibit 27)</p> <ul data-bbox="850 625 1921 1388" style="list-style-type: none"> • Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position of the fluidic pathway, by way of the void of the corrugated surface, the fluidic pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber. • Claim 2. The cartridge of claim 1, wherein the first layer is a unitary construction comprising a reagent port, the fluid port, and a detection chamber, and wherein the fluidic pathway is coupled to the reagent port, the fluid port, and the detection chamber. • Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate

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		<p>is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate.</p> <ul style="list-style-type: none"> • Claim 10. The cartridge of claim 8, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the second detection chamber, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port. • U.S. Patent No. 9,403,165 at 3:27-32 (“As shown in FIGS. 1B and 1C, the top layer 110 preferably comprises a set of sample port-reagent port pairs 112, a fluid port 118, a vent region 190, a heating region 195 crossing a capture segment 166 of a fluidic pathway 165, and a set of detection chambers 116.”) • U.S. Patent No. 9,403,165 at 1A.


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		 <p style="text-align: center;">FIG. 1A</p> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at FIG. 1C .  <p style="text-align: center;">FIG. 1C</p> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at 3:53-67 (“Each sample-port reagent port pair 113 of an embodiment of the top layer 110 also comprises a reagent port 115, as

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		<p>shown in FIG. 1A. The reagent port 115 in a sample port-reagent port pair 113 functions to receive a volume of fluid comprising a reagent used in molecular diagnostics, for delivery of the volume of fluid comprising a reagent to a portion of a fluidic pathway 165 coupled to the sample port-reagent port pair 113. In a specific embodiment, the volume of fluid comprising a reagent used in molecular diagnostics is a sample of reconstituted molecular diagnostic reagents mixed with nucleic acids released and isolated using the microfluidic cartridge 100; however, the volume of fluid comprising a reagent used in molecular diagnostics may alternatively be any appropriate fluid comprising reagents used in molecular diagnostics.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,403,165 at 13:23-30 (“The set of fluidic pathways 160 of the microfluidic cartridge 100 functions to provide a fluid network into which volumes of sample fluids, reagents, buffers and/or gases used in a molecular diagnostics protocol may be delivered, out of which waste fluids may be eliminated, and by which processed nucleic acid samples may be delivered to a detection chamber for analysis, which may include amplification and/ or detection.”) • U.S. Patent No. 9,403,165 at 17:17-33 (“Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”) • U.S. Patent No. 9,403,165 at 21:33-39 (“Additionally, the set of fluidic

Claim	Claim Language	Infringement Evidence
		<p>pathways 160 of the microfluidic cartridge 100 may comprise virtually any number of fluidic pathway 165 and/or the set of Detection chambers 116 may comprise virtually any number of Detection chambers 116 as can practically be integrated into the microfluidic cartridge 100. In one specific embodiment, the set of fluidic pathways 160 may comprise twelve fluidic pathways 165, four of which are shown in FIG. 9.")</p> <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module. • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater.

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) • U.S. Patent No. 9,050,594 at 3:1-6 (“The system 100 thus functions to receive biological samples containing nucleic acids (i.e., impure nucleic acid samples), separate nucleic acids from the biological samples, and analyze nucleic acid samples according to at least one molecular diagnostic protocol (e.g., PCR).”) • U.S. Patent No. 9,050,594 at 10:29-34 (“The heating and cooling subsystem 150 of the molecular diagnostic module 130 comprises a cartridge heater 153, a fan 155, and a set of detection chamber heaters 157 and functions to controllably heat portions of a microfluidic cartridge 210 for processing of a biological sample containing nucleic acids according to a molecular diagnostic protocol.”) • U.S. Patent No. 9,050,594 at 23:28-41 (“The embodiment of the liquid handling system 100 is further configured to facilitate separation of a set of nucleic acids from the magnetic bead-samples, by dispensing a wash solution, a release solution, and/or air into the molecular diagnostic module 130, by the nozzle 149 coupled to the linear actuator 146, at appropriate stages, aspirate the set of nucleic acids from the molecular diagnostic module 130, combine the set of nucleic acids with a set of molecular diagnostic reagents using an assay

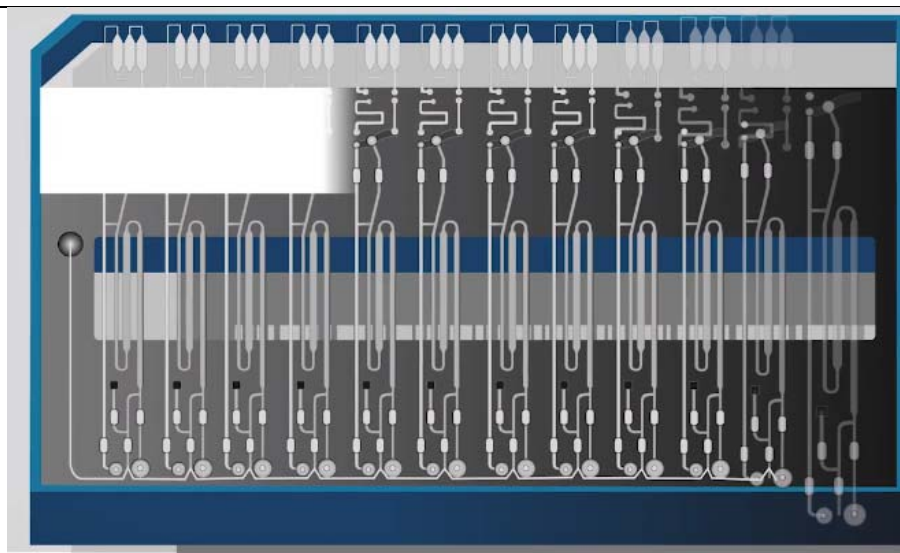
Claim	Claim Language	Infringement Evidence
		<p>strip 190, and dispense the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the molecular diagnostic module 130 for further processing and analysis. [Other embodiments of the liquid handling system 250 may be configured to perform alternative molecular diagnostic assay protocols and/or dispense and aspirate alternative fluids into and from other elements supporting a molecular diagnostic protocol.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 27:16-26 (“transferring each of the set of nucleic acid-reagent mixtures, through the corresponding fluidic pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers S460; and receiving light from the set of nucleic acid-reagent mixtures S470. The method 400 may farther comprise generating a set of data based on light received form the set of nucleic acid-reagent mixtures S480. The method 400 functions to isolate and extract a set of nucleic acid volumes from a biological sample, and to facilitate analysis of the nucleic acid volumes according to at least one molecular diagnostic protocol.”) • U.S. Patent No. 9,050,594 at 31:32-37 (“Step S460 recites transferring each of the set of nucleic acid-reagent mixtures, through the corresponding fluidic pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers, which functions to deliver the set of nucleic acid-reagent mixtures to an isolated detection chamber for further processing and analysis.”)

1(d)	the first and second modules comprising: a bay configured to removably receive a housing comprising a plurality of process chambers that are maintained at a same height relative to one another when the housing is received in the bay,	<p>The accused system comprises the first and second modules comprising: a bay configured to removably receive a housing comprising a plurality of process chambers that are maintained at a same height relative to one another when the housing is received in the bay.</p> <p><i>NeuMoDx Molecular N288 System</i>, http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ TECHNOLOGY” hyperlink at https://player.vimeo.com/video/281470603. (Exhibit 17)</p> <ul style="list-style-type: none"> At 4:17 (showing a plurality of multi-lane microfluidic cartridges in a plurality of receiving bays)  <ul style="list-style-type: none"> at 4:55-5:00 (showing a plurality of multi-lane microfluidic cartridges in a plurality of receiving bays)
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NeuMoDx Molecular N96 and N288 Overview and Animation, NEUMODX (Nov. 6, 2018, 3:50 PM), <http://www.neumodx.com/our-solutions/> - linking to “VIDEO | NeuMoDx™ WORKFLOW” hyperlink at <https://player.vimeo.com/video/299307936>. (Exhibit 16)

- “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains **12 independent lanes which allows for processing of up to 12 samples simultaneously.**” *Id.* at 1:49-1:59



- “Once the crude lysate is dispensed, a series of valves **directs the flow to the s-channel, where the paramagnetic beads are captured** utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” *Id.* at 2:28-2:39.
- *Id.* at 2:28 (showing lysate in the s-channel). “Once the crude lysate is dispensed, a series of valves **directs the flow to the s-channel**, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” *Id.* at 2:28-2:39.
- *Id.* at 2:28 (showing lysate in the s-channel).



- “A precise volume of air is then applied to remove any remaining liquid into the waste chamber. NeuMoDx wash solution is pumped via the fluid port into the microfluidic cartridge to remove all unbound material, followed by another volume of air to remove excess wash solution. High pH NeuMoDx release reagent is dispensed into the **s-channel** to cover the beads, and heat is applied to the denaturation process, resulting in released nucleic acid or eluate.” *Id.* at 2:39-3:12.

US9382532 (Exhibit 52)

- Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; **receiving a cartridge at a**

		<p>cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 10. The method of claim 3, wherein washing the set of moiety-bound nucleic acid particles comprises aspirating the moiety-sample mixture; receiving the cartridge at the cartridge receiving module comprising the set of pins and a cam card interfacing with the set of pins; transitioning the cartridge to an active configuration that disposes the cartridge proximal the set of pins; displacing the first subset of the set of pins in the active configuration of the cartridge, upon translation of the cam card relative to the set of pins, thereby occluding the fluidic pathway of the cartridge at a set of occlusion positions; delivering the moiety-sample mixture into the fluidic pathway, wherein the fluidic pathway is configured to pass through a magnetic field and is coupled to a waste chamber, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field; and delivering a wash solution through the fluidic pathway and into the waste chamber in a continuous flow operation. • Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process
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		<p>chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second subset of the set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction.</p> <ul style="list-style-type: none"> • Claim 19. A method for nucleic acid isolation from a biological sample, comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution includes a set of affinity moiety-coated microparticles, comprising a set of microparticles amide-bonded to at least one of Poly(allylamine) of molecular weight <30,000 Da and Polypropylenimine tetramine dendrimer Generation 1; producing a moiety-sample mixture upon combination of the binding moiety solution with the biological sample; producing a set of moiety-bound nucleic acid particles upon incubation of the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of the set of pins includes reversing displacement
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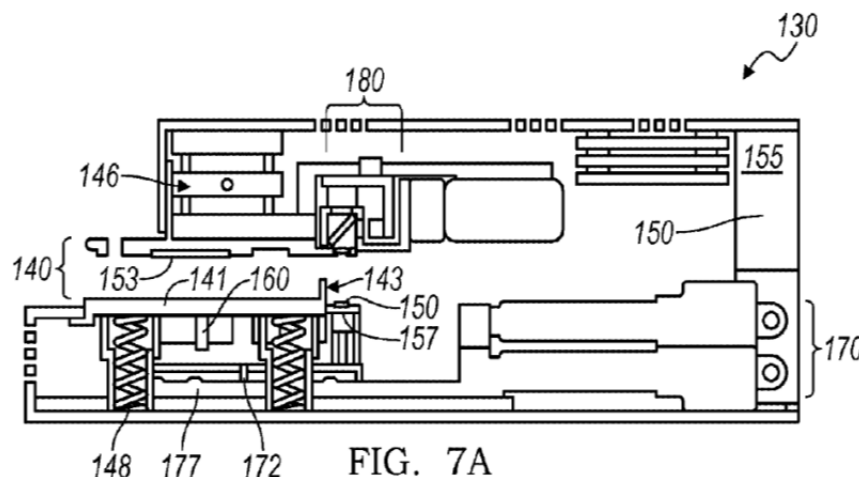
		<p>of at least one pin of the first subset of the set of pins, and reversing occlusion of a portion of the fluidic pathway.</p> <ul style="list-style-type: none"> Patent No. 9,382,532 at 23:23-28 (“In a specific example, the valve actuation subsystem 170 comprises 12 sets of pins 172 configured to selectively occlude 12 fluidic pathways 212 of a microfluidic cartridge 210 aligned within the molecular diagnostic module; however, other embodiments may comprise any appropriate number of sets of pins 172.”) <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position of the fluidic pathway, by way of the void of the corrugated surface, the fluidic pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber. U.S. Patent No. 9,403,165 at 7:66-8:22. “The top layer 110 of the microfluidic cartridge 100 may further comprise a set of cartridge-aligning indentations 180, which function to align the microfluidic cartridge 100 as it moves through an external module. As shown in FIG. 2 the set of cartridge-aligning indentations 180 are preferably located such that they do not interfere with any ports 112, 118, the heating region, 195, the vent region 190, and/or the set of detection chambers 116. In an embodiment, the top layer 110 of the microfluidic cartridge preferably comprises at least four cartridge-aligning indentations, located at points on the periphery of the top layer 110, and the cartridge-aligning indentations are configured to be recessed regions configured to mate with alignment pins in a system external to the microfluidic cartridge 100. Alternatively, the cartridge-
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		<p>aligning indentations may be grooves, such that the microfluidic cartridge 100 accurately slides into position along the grooves within a system external to the microfluidic cartridge 100. In yet another alternative embodiment, the set of cartridge-aligning indentations 180 may be any appropriate indentations that allow for positioning of the microfluidic cartridge 100 within an external system. However, the microfluidic cartridge 100 may altogether omit the set of cartridge-aligning indentations 180, and rely upon other features of the microfluidic cartridge 100 to facilitate alignment.”</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,403,165 at 10:35-42 (“In an embodiment of the waste chamber 130 with a corrugated surface 137, at least two ridges of the corrugated surface 137 are preferably the same height, such that the microfluidic cartridge 100 sits substantially level on a flat base. In an alternative embodiment, all ridges of the corrugated surface 137 of the waste chamber 130 are identical, for structural symmetry, and in yet another embodiment, the waste chamber 130 may not have a corrugated surface 137.”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of
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		<p>sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer.</p> <ul style="list-style-type: none"> • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and
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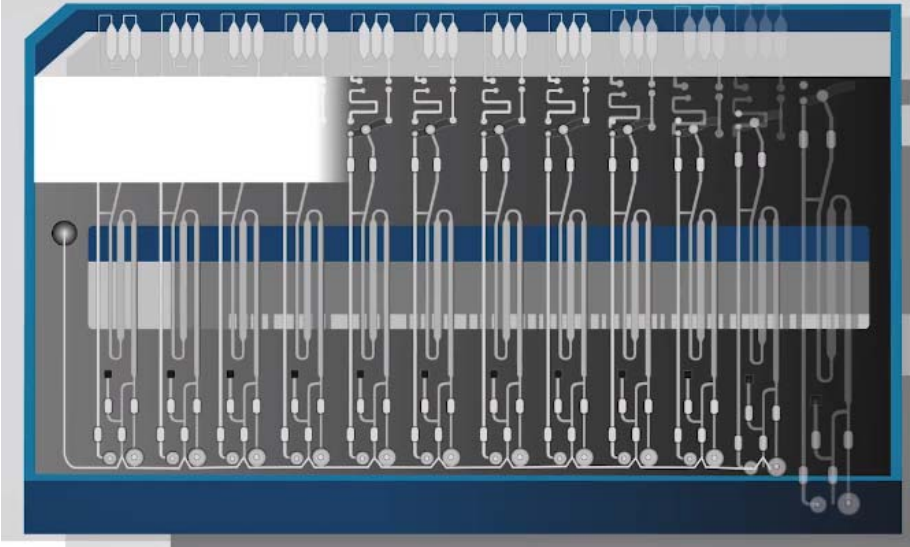
reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”)

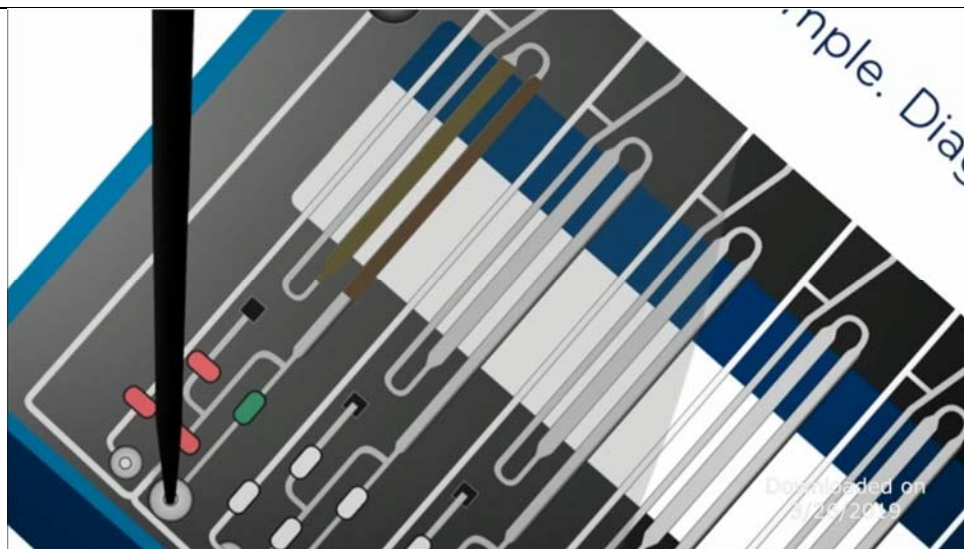
- U.S. Patent No. 9,050,594 at 2:49-58 (“As shown in FIGS. 1A-1B and 7A, an embodiment of a system 100 for processing and detecting nucleic acids comprises: a capture plate 110 configured to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119; **a molecular diagnostic module 130 comprising a microfluidic cartridge receiving module 140**, heating and cooling subsystem 150, a magnet 160, a valve actuation subsystem 170, an optical subsystem 180; and an assay strip 190 configured to facilitate mixing of molecular diagnostic reagents with a nucleic acid volume.”)
- U.S. Patent No. 9,050,594 at 7A.



- U.S. Patent No. 9,050,594 at 22:61-23:20 (“The **microfluidic cartridge 210** is preferably configured to be received and manipulated by the **molecular diagnostic module 130**, such that the cartridge receiving module 140 of the molecular diagnostic module 130 **receives and aligns the microfluidic cartridge 210 within the molecular diagnostic module 130**, the heating and cooling subsystem 150 of the molecular diagnostic module 130 is configured to transfer heat to the heating region 224 of the microfluidic cartridge 210, and the magnet 160

		<p>of the molecular diagnostic module 130 is configured to be received by the magnet housing region 218 of the microfluidic cartridge 210 to provide a magnetic field for separation of nucleic acids. The elastomeric layer 217 of the microfluidic cartridge 210 is also preferably configured to be occluded at a set of occlusion positions 226 by the valve actuation subsystem 170 of the molecular diagnostic module, in order to occlude portions of a fluidic pathway 220 of the microfluidic cartridge 210 for processing of a set of biological samples. The optical subsystem 180 of the molecular diagnostic module 130 is further configured to align with the set of detection chambers 213 of the microfluidic cartridge 210, to facilitate analysis of a set of nucleic acid samples.”)</p>
1(e)	the plurality of process chambers aligned along a first axis when the housing is received in the bay,	<p>The accused system comprises the first and second modules comprising: a bay configured to removably receive a housing comprising a plurality of process chambers that are maintained at a same height relative to one another when the housing is received in the bay, the plurality of process chambers aligned along a first axis when the housing is received in the bay.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59

		 <ul style="list-style-type: none"> • “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” <i>Id.</i> at 2:28-2:39. • <i>Id.</i> at 2:28 (showing lysate in the s-channel).
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US9382532 (Exhibit 52)

- Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; **receiving a cartridge at a cartridge receiving module** comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; **washing the set of moiety-**

		<p>bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 10. The method of claim 3, wherein washing the set of moiety-bound nucleic acid particles comprises aspirating the moiety-sample mixture; receiving the cartridge at the cartridge receiving module comprising the set of pins and a cam card interfacing with the set of pins; transitioning the cartridge to an active configuration that disposes the cartridge proximal the set of pins; displacing the first subset of the set of pins in the active configuration of the cartridge, upon translation of the cam card relative to the set of pins, thereby occluding the fluidic pathway of the cartridge at a set of occlusion positions; delivering the moiety-sample mixture into the fluidic pathway, wherein the fluidic pathway is configured to pass through a magnetic field and is coupled to a waste chamber, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field; and delivering a wash solution through the fluidic pathway and into the waste chamber in a continuous flow operation. • Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins,
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		<p>each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second subset of the set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction.</p> <ul style="list-style-type: none"> • Claim 19. A method for nucleic acid isolation from a biological sample, comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution includes a set of affinity moiety-coated microparticles, comprising a set of microparticles amide-bonded to at least one of Poly(allylamine) of molecular weight <30,000 Da and Polypropylenimine tetramine dendrimer Generation 1; producing a moiety-sample mixture upon combination of the binding moiety solution with the biological sample; producing a set of moiety-bound nucleic acid particles upon incubation of the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of the set of pins includes reversing displacement of at least one pin of the first subset of the set of pins, and reversing occlusion of a portion of the fluidic pathway. • Patent No. 9,382,532 at 23:23-28 (“In a specific example, the valve actuation subsystem 170 comprises 12 sets of pins 172 configured to selectively occlude 12 fluidic pathways 212 of a microfluidic cartridge 210 aligned within the
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		<p>molecular diagnostic module; however, other embodiments may comprise any appropriate number of sets of pins 172.”)</p> <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> • Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position of the fluidic pathway, by way of the void of the corrugated surface, the fluidic pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber. • Claim 4. The cartridge of claim 3, wherein the fluidic pathway comprises a capture segment, downstream of the sample port and configured to cross the magnet housing region multiple times. • U.S. Patent No. 9,403,165 at 3:27-32 (“As shown in FIGS. 1B and 1C, the top layer 110 preferably comprises a set of sample port-reagent port pairs 112, a fluid port 118, a vent region 190, a heating region 195 crossing a capture segment 166 of a fluidic pathway 165, and a set of detection chambers 116.”) • U.S. Patent No. 9,403,165 at 5:6-9 (“The heating region 195 is preferably a recessed fixed region of the top layer 110, downstream of the sample port-reagent port pairs 112, as shown in FIGS. 1A and 18.”) • U.S. Patent No. 9,403,165 at 1A.
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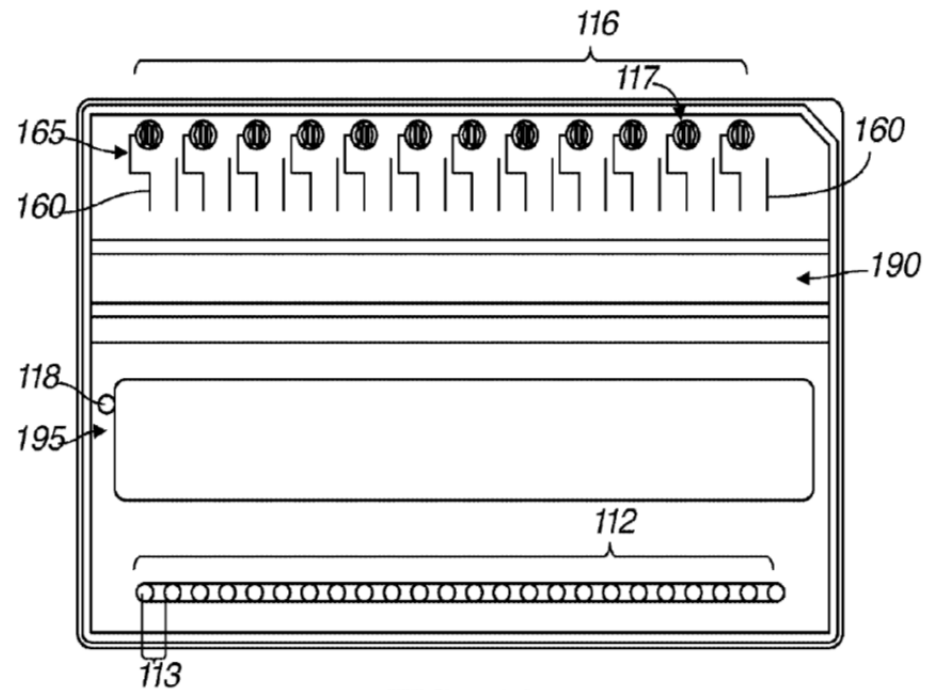


FIG. 1A

- U.S. Patent No. 9,403,165 at FIG. 1C .

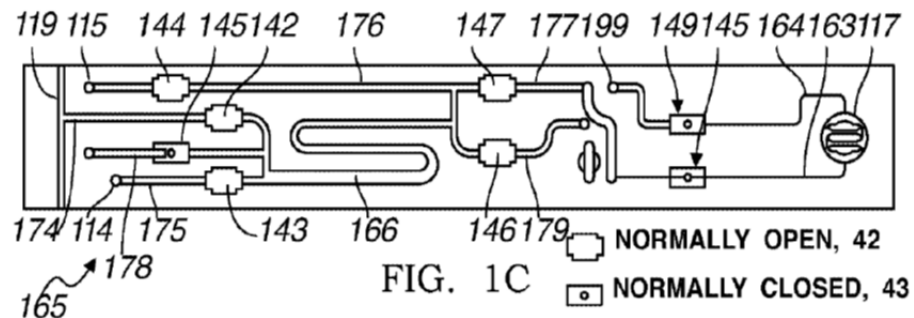


FIG. 1C

- U.S. Patent No. 9,403,165 at 7:66-8:22. “The top layer 110 of the microfluidic cartridge 100 may further comprise a set of cartridge-aligning indentations 180, which function to **align the microfluidic cartridge 100** as it moves through an

		<p>external module. As shown in FIG. 2 the set of cartridge-aligning indentations 180 are preferably located such that they do not interfere with any ports 112, 118, the heating region, 195, the vent region 190, and/or the set of detection chambers 116. In an embodiment, the top layer 110 of the microfluidic cartridge preferably comprises at least four cartridge-aligning indentations, located at points on the periphery of the top layer 110, and the cartridge-aligning indentations are configured to be recessed regions configured to mate with alignment pins in a system external to the microfluidic cartridge 100. Alternatively, the cartridge-aligning indentations may be grooves, such that the microfluidic cartridge 100 accurately slides into position along the grooves within a system external to the microfluidic cartridge 100. In yet another alternative embodiment, the set of cartridge-aligning indentations 180 may be any appropriate indentations that allow for positioning of the microfluidic cartridge 100 within an external system. However, the microfluidic cartridge 100 may altogether omit the set of cartridge-aligning indentations 180, and rely upon other features of the microfluidic cartridge 100 to facilitate alignment.”</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,403,165 at 10:35-42 (“In an embodiment of the waste chamber 130 with a corrugated surface 137, at least two ridges of the corrugated surface 137 are preferably the same height, such that the microfluidic cartridge 100 sits substantially level on a flat base. In an alternative embodiment, all ridges of the corrugated surface 137 of the waste chamber 130 are identical, for structural symmetry, and in yet another embodiment, the waste chamber 130 may not have a corrugated surface 137.”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of
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		<p>the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate
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		<p>and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 2:49-58 (“As shown in FIGS. 1A-1B and 7A, an embodiment of a system 100 for processing and detecting nucleic acids comprises: a capture plate 110 configured to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119; a molecular diagnostic module 130 comprising a microfluidic cartridge receiving module 140, heating and cooling subsystem 150, a magnet 160, a valve actuation subsystem 170, an optical subsystem 180; and an assay strip 190 configured to facilitate mixing of molecular diagnostic reagents with a nucleic acid volume.”) • U.S. Patent No. 9,050,594 at 3:20-33 (“The liquid handling system 250 then aspirates substantially all of each sample of the set of lysed biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate no [sic], and dispenses the set of magnetic bead-samples into a microfluidic cartridge 210, aligned within a cartridge receiving module 140 of a molecular diagnostic module 130, and configured to be manipulated by the molecular diagnostic module 130. A heating and cooling subsystem 150, a magnet 160, and a valve actuation subsystem 170 of the molecular diagnostic module 130 then facilitate separation of a set of nucleic acids from the magnetic bead-samples, as the liquid handling system 250 dispenses wash solutions, release solutions, and/or air at appropriate stages.”) • U.S. Patent No. 9,050,594 at 7A.
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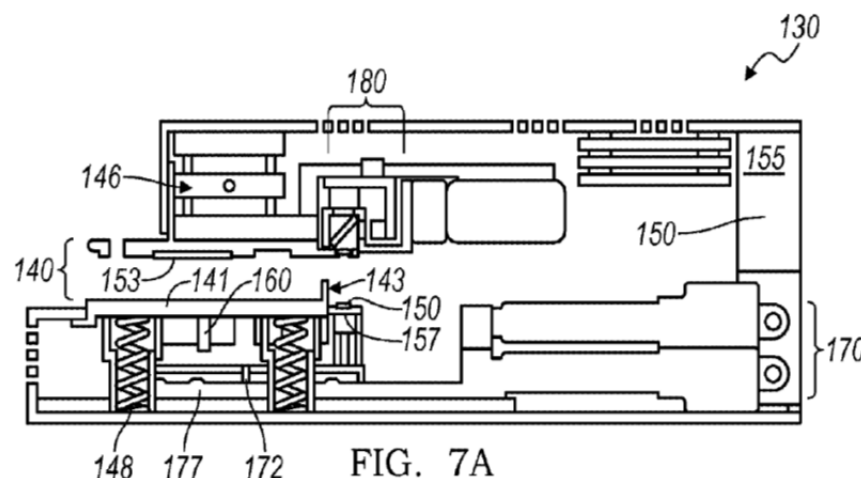



FIG. 7A

- U.S. Patent No. 9,050,594 at 11:56-12:3 (“The set of detection chamber heaters 157 functions to individually heat detection chambers of a set of detection chambers 213 within a microfluidic cartridge 210. Each detection chamber heater in the set of detection chamber heaters 157 is preferably configured to heat one side of one detection chamber in the set of detection chambers 213, and is preferably located such that **the extended configuration 146b of the linear actuator 146 of the cartridge receiving module 140** puts a detection chamber in proximity to a detection chamber heater. As mentioned above, the set of detection chamber heaters 157 is preferably coupled to springs or an elastomeric layer to ensure direct contact between the set of detection chamber heaters and a set of detection chambers, without compressively damaging the set of detection chamber heater 157.”)
- U.S. Patent No. 9,050,594 at 22:61-23:5 (“The **microfluidic cartridge 210 is preferably configured to be received and manipulated by the molecular diagnostic module 130**, such that the cartridge receiving module 140 of the molecular diagnostic module 130 **receives and aligns the microfluidic cartridge 210 within the molecular diagnostic module 130**, the heating and cooling subsystem 150 of the molecular diagnostic module 130 is configured to transfer heat to the heating region 224 of the microfluidic cartridge 210, and the magnet 160 of the molecular diagnostic module 130 is configured to be received by the magnet housing region 218 of the microfluidic cartridge 210 to provide a magnetic field for

		separation of nucleic acids.”)
1(f)	the bay comprising one or more complementary registration members configured to receive the housing in a single orientation when the housing is received in the bay	<p>The accused system comprises the first and second modules comprising: a bay configured to removably receive a housing comprising a plurality of process chambers that are maintained at a same height relative to one another when the housing is received in the bay, the plurality of process chambers aligned along a first axis when the housing is received in the bay, the bay comprising one or more complementary registration members configured to receive the housing in a single orientation when the housing is received in the bay.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ TECHNOLOGY” hyperlink at https://player.vimeo.com/video/281470603. (Exhibit 16)</p> <ul style="list-style-type: none"> At 4:17 (showing a plurality of multi-lane microfluidic cartridges in a plurality of receiving bays)  <ul style="list-style-type: none"> at 4:55-5:00 (showing a plurality of multi-lane microfluidic cartridges in a plurality of receiving bays)



On information and belief, the accused system comprises the first and second modules comprising: a bay configured to removably receive a housing comprising a plurality of process chambers that are maintained at a same height relative to one another when the housing is received in the bay, the plurality of process chambers aligned along a first axis when the housing is received in the bay, the bay comprising one or more complementary registration members configured to receive the housing in a single orientation when the housing is received in the bay.

US9403165 (Exhibit 27)

		<ul style="list-style-type: none"> • Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position of the fluidic pathway, by way of the void of the corrugated surface, the fluidic pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber. • U.S. Patent No. 9,403,165 at 7:66-8:22 (“The top layer 110 of the microfluidic cartridge 100 may further comprise a set of cartridge-aligning indentations 180, which function to align the microfluidic cartridge 100 as it moves through an external module. As shown in FIG. 2 the set of cartridge-aligning indentations 180 are preferably located such that they do not interfere with any ports 112, 118, the heating region, 195, the vent region 190, and/or the set of detection chambers 116. In an embodiment, the top layer 110 of the microfluidic cartridge preferably comprises at least four cartridge-aligning indentations, located at points on the periphery of the top layer 110, and the cartridge-aligning indentations are configured to be recessed regions configured to mate with alignment pins in a system external to the microfluidic cartridge 100. Alternatively, the cartridge-aligning indentations may be grooves, such that the microfluidic cartridge 100 accurately slides into position along the grooves within a system external to the microfluidic cartridge 100. In yet another alternative embodiment, the set of cartridge-aligning indentations 180 may be any appropriate indentations that allow for positioning of the microfluidic cartridge 100 within an external system. However, the microfluidic cartridge 100 may altogether omit the set of cartridge-aligning indentations 180, and rely upon other features of the microfluidic cartridge 100 to facilitate alignment.”) • U.S. Patent No. 9,403,165 at 10:35-42 (“In an embodiment of the waste chamber
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130 with a corrugated surface 137, at least two ridges of the corrugated surface 137 are preferably the same height, **such that the microfluidic cartridge 100 sits substantially level on a flat base.** In an alternative embodiment, all ridges of the corrugated surface 137 of the waste chamber 130 are identical, for structural symmetry, and in yet another embodiment, the waste chamber 130 may not have a corrugated surface 137.”)

- U.S. Patent No. 9,403,165 at 12:23-28 (“In an embodiment of the microfluidic cartridge 100 where the waste chamber 130 has a corrugated surface, the bottom layer 170 preferably only seals voids defining the waste chamber 130, such that non-waste chamber regions (i.e. non-waste housing regions) are not covered by the bottom layer 170.”)
- U.S. Patent No. 9,403,165 at FIG. 4.

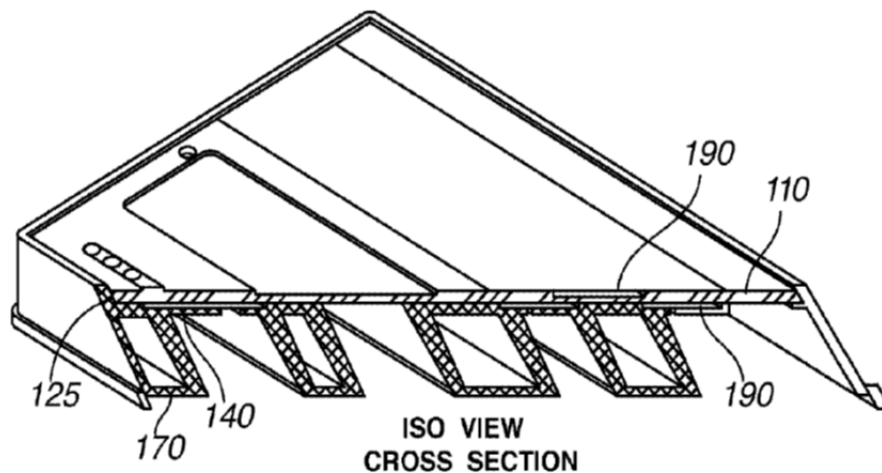


FIG. 4

US9382532 (Exhibit 52)

- Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises

		<p>Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 10. The method of claim 3, wherein washing the set of moiety-bound nucleic acid particles comprises aspirating the moiety-sample mixture; receiving the cartridge at the cartridge receiving module comprising the set of pins and a cam card interfacing with the set of pins; transitioning the cartridge to an active configuration that disposes the cartridge proximal the set of pins; displacing the first subset of the set of pins in the active configuration of the cartridge, upon translation of the cam card relative to the set of pins, thereby occluding the fluidic pathway of the cartridge at a set of occlusion positions; delivering the moiety-sample mixture into the fluidic pathway, wherein the fluidic pathway is configured to pass through a magnetic field and is coupled to a waste chamber, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field; and delivering a wash solution through the fluidic pathway and into the waste chamber in a continuous flow operation. • Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method
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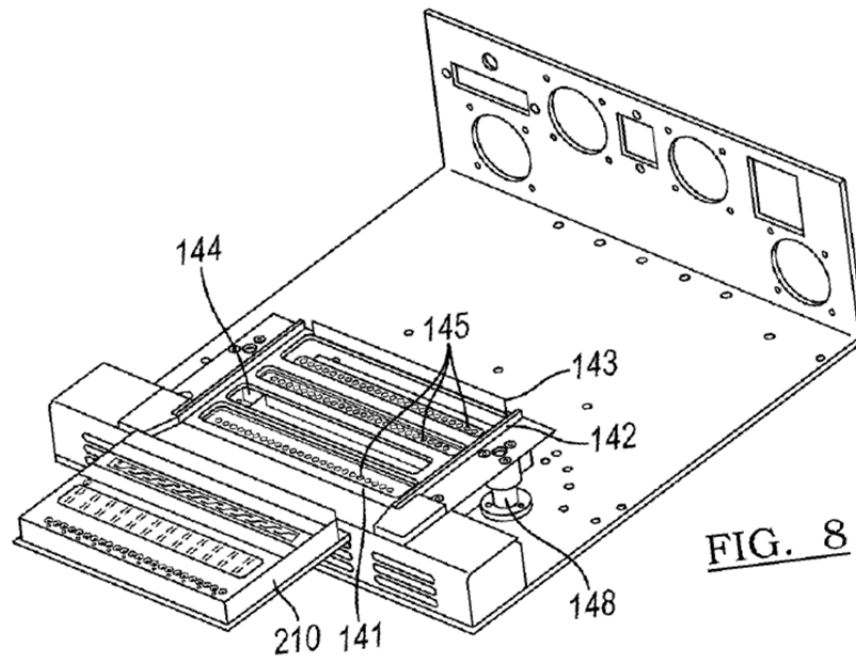
		<p>comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second subset of the set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction.</p> <ul style="list-style-type: none"> • Claim 19. A method for nucleic acid isolation from a biological sample, comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution includes a set of affinity moiety-coated microparticles, comprising a set of microparticles amide-bonded to at least one of Poly(allylamine) of molecular weight <30,000 Da and Polypropylenimine tetramine dendrimer Generation 1; producing a moiety-sample mixture upon combination of the binding moiety solution with the biological sample; producing a set of moiety-bound nucleic acid particles upon incubation of the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound
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		<p>nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of the set of pins includes reversing displacement of at least one pin of the first subset of the set of pins, and reversing occlusion of a portion of the fluidic pathway.</p> <ul style="list-style-type: none"> Patent No. 9,382,532 at 23:23-28 (“In a specific example, the valve actuation subsystem 170 comprises 12 sets of pins 172 configured to selectively occlude 12 fluidic pathways 212 of a microfluidic cartridge 210 aligned within the molecular diagnostic module; however, other embodiments may comprise any appropriate number of sets of pins 172.”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic
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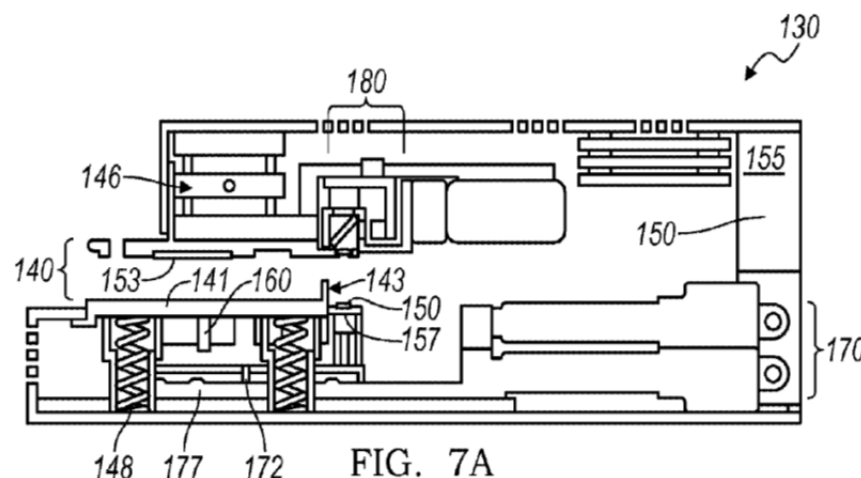
		<p>pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 7:53-8:6 (“As shown in FIG. 9A, the cartridge receiving module 140 of the molecular diagnostic module 130 comprises a cartridge platform 141 including a cartridge loading guiderail 142, a cartridge stop 143, a magnet receiving slot 144, and a set of valve actuation slots 145; a linear actuator 146 configured to displace a microfluidic cartridge 210 resting on the cartridge platform 141, and a set of springs 148 coupled to the cartridge platform 141. The cartridge receiving module 140 thus functions to receive, align, and compress a microfluidic cartridge 210 for processing of a biological sample according to a molecular diagnostic assay protocol. As shown in FIGS. 7A-7C, the cartridge platform 141 is preferably configured to receive a microfluidic cartridge 210 along a cartridge loading guiderail 142 until it reaches a cartridge stop 143, and be vertically displaced by the linear actuator 146, which places a biasing force against the set of springs 148 coupled to the cartridge platform 141. The magnet receiving slot 144 and the set of valve actuation slots 145 provide access, by a magnet 160 and a valve actuation subsystem 170, to the microfluidic cartridge 210, as the microfluidic cartridge is vertically displaced by the linear actuator 146.”) • U.S. Patent No. 9,050,594 at 8:7-35 (“The cartridge platform 141 includes a cartridge loading guiderail 142, a cartridge stop 143, a magnet receiving slot 144, and a set of valve actuation slots 145, and functions to receive and align a microfluidic cartridge 210, while providing access to the microfluidic cartridge 210 by a magnet 160 and a valve actuation subsystem 170. As shown in FIG. 8, an embodiment of the cartridge platform 141 includes a pair of parallel cartridge loading guiderails 142, initiating at a pair of inwardly tapering protrusions configured to guide a microfluidic cartridge toward the pair of parallel cartridge loading guiderails 142, and spanning two short edges of the cartridge platform 141. The embodiment of the cartridge platform 141 also includes a cartridge stop 143 comprising a vertical tab oriented perpendicular to the cartridge loading guiderails 142, and spanning a long edge of the cartridge platform. Preferably, the cartridge loading guiderails 142 and the cartridge stop 143 are
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configured such that a microfluidic cartridge 210 slides between the cartridge loading guiderails 142 and hits the cartridge stop 143 to signal proper alignment. Alternatively, the cartridge loading guiderails 142 and the cartridge stop 143 may be configured such that a microfluidic cartridge slides over or along the cartridge loading guiderails 142, after which the cartridge stop 143 couples to a portion of the microfluidic cartridge 210 to **ensure proper alignment of the microfluidic cartridge**. Additional variations of the cartridge loading guiderails 142 and the cartridge stop 143 may be used to enable reception and alignment of a microfluidic cartridge 210 by the molecular diagnostic module 130, and are known by those skilled in the art.”)

- U.S. Patent No. 9,050,594 at FIG. 8.



- U.S. Patent No. 9,050,594 at 7A.



- U.S. Patent No. 9,050,594 at 22:61-23:20 (“The **microfluidic cartridge 210 is preferably configured to be received and manipulated by the molecular diagnostic module 130**, such that the cartridge receiving module 140 of the molecular diagnostic module 130 **receives and aligns the microfluidic cartridge 210 within the molecular diagnostic module 130**, the heating and cooling subsystem 150 of the molecular diagnostic module 130 is configured to transfer heat to the heating region 224 of the microfluidic cartridge 210, and the magnet 160 of the molecular diagnostic module 130 is configured to be received by the magnet housing region 218 of the microfluidic cartridge 210 to provide a magnetic field for separation of nucleic acids. The elastomeric layer 217 of the microfluidic cartridge 210 is also preferably configured to be occluded at a set of occlusion positions 226 by the valve actuation subsystem 170 of the molecular diagnostic module, in order to occlude portions of a fluidic pathway 220 of the microfluidic cartridge 210 for processing of a set of biological samples. The optical subsystem 180 of the molecular diagnostic module 130 is further **configured to align with the set of detection chambers 213 of the microfluidic cartridge 210**, to facilitate analysis of a set of nucleic acid samples.”)

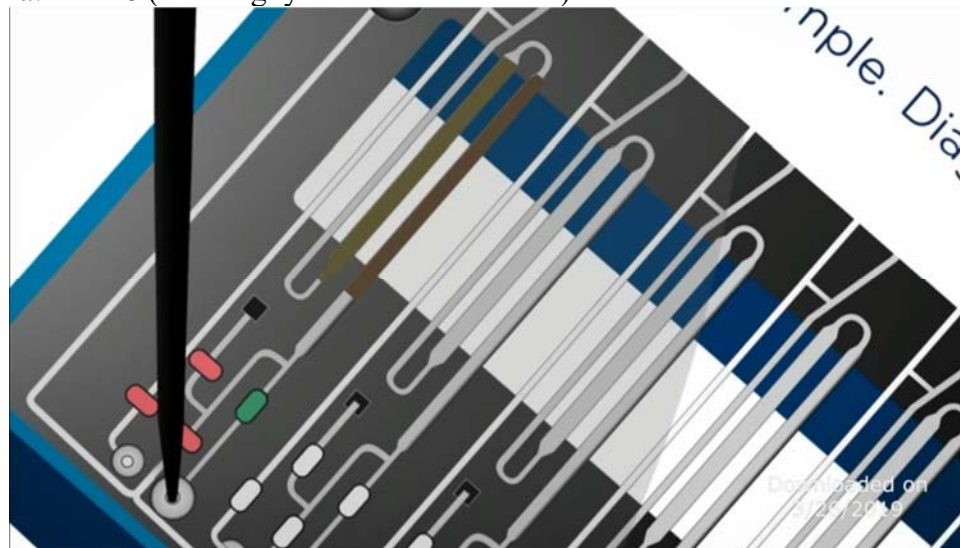
1(g)	the first module further comprising a magnetic	In the accused system, the first module further comprises a magnetic separator positioned to apply a magnetic force to a first side of the plurality of process chambers when the
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separator positioned to apply a magnetic force to a first side of the plurality of process chambers when the housing is received in the bay

housing is received in the bay.

NeuMoDx Molecular N96 and N288 Overview and Animation, NEUMODx (Nov. 6, 2018, 3:50 PM), <http://www.neumodx.com/our-solutions/> - linking to “VIDEO | NeuMoDx™ WORKFLOW” hyperlink at <https://player.vimeo.com/video/299307936>. (Exhibit 16)

- “Once the crude lysate is dispensed, a series of valves **directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel**, with the excess solution flowing into a self-contained waste chamber.” *Id.* at 2:28-2:39.
- *Id.* at 2:28 (showing lysate in the s-channel).



US9382532 (Exhibit 52)

- Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of

		<p>microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 5. The method of claim 3, wherein separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture. • Claim 6. The method of claim 5, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety-sample mixture from the process chamber; occluding the fluidic pathway of the cartridge-at a set of occlusion positions upon displacement of pins of the set of pins to generate a path through a magnetic field, and to a waste chamber; and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber. • Claim 10. The method of claim 3, wherein washing the set of moiety-bound nucleic acid particles comprises aspirating the moiety-sample mixture; receiving the cartridge at the cartridge receiving module comprising the set of pins and a cam
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		<p>card interfacing with the set of pins; transitioning the cartridge to an active configuration that disposes the cartridge proximal the set of pins; displacing the first subset of the set of pins in the active configuration of the cartridge, upon translation of the cam card relative to the set of pins, thereby occluding the fluidic pathway of the cartridge at a set of occlusion positions; delivering the moiety-sample mixture into the fluidic pathway, wherein the fluidic pathway is configured to pass through a magnetic field and is coupled to a waste chamber, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field; and delivering a wash solution through the fluidic pathway and into the waste chamber in a continuous flow operation..</p> <ul style="list-style-type: none"> • Claim 14. The method of claim 13, further comprising capturing the set of moiety-bound nucleic acid particles within the magnetic field and aspirating the nucleic acid sample from the fluidic pathway. • Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20uL of an elution solution characterized by a pH greater than 10, in coordination with
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		<p>displacement of a second subset of the set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction.</p> <ul style="list-style-type: none"> • Claim 18. The method of claim 17, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety-sample mixture from the process chamber; occluding the fluidic pathway of the cartridge at a set of occlusion positions upon displacement of the first subset of the set of pins to generate a path through a magnetic field, and to a waste chamber of the cartridge; and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber. • Patent No. 9,382,532 at 4:35-44 (“In a specific example of this variation of Step S110, the microparticles are magnetic beads (e.g., magnetic, paramagnetic [sic], superparamagnetic) with any suitable hydrophilicity (e.g., hydrophobic, hydrophilic), wherein the magnetic beads are coated with the affinity moiety and simultaneously received within the process chamber along with a low-pH buffer solution, proteolytic enzymes, and lytic reagents. In this specific example, magnetic separation can be used to facilitate further processing and isolation of nucleic acids bound to the affinity moieties coupled to magnetic beads.”) • Patent No. 9,382,532 at 6:41-59 (“Step S140 recites separating the moiety-bound nucleic acid volume from the waste volume, and functions to compact or concentrate microparticles coupled to the target nucleic acid(s), by way of the affinity moieties, in order to facilitate removal of the waste volume from the moiety-bound nucleic acid volume. Preferably, the moiety-bound nucleic acid volume is separated using a magnetic-separation method; however the moiety-bound nucleic acid volume can alternatively be separated using methods based upon microparticle size, mass, and/or density (e.g., centrifugation, sedimenting, filtering), and/or focusing methods (e.g., electric field focusing, laser based focusing). Separation in Step S140 can, however, be performed using any other suitable method. In a first variation, wherein the microparticles coupled with affinity moieties have magnetic properties, a magnetic field can be applied to retain the nucleic acid-bound microparticles of the moiety-bound nucleic acid volume, while the waste volume (e.g., cellular debris and other unbound material)
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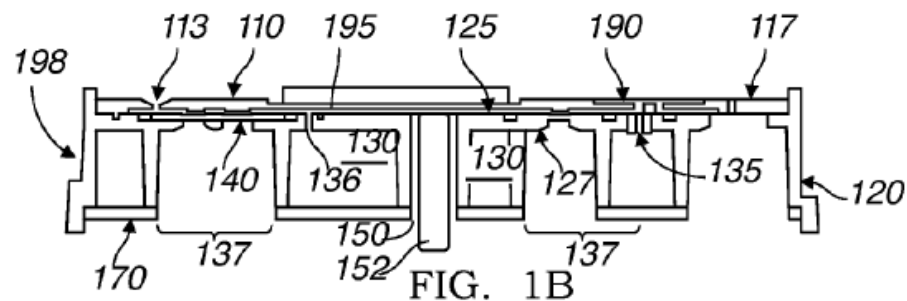
		<p>is substantially removed by aspiration.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at 7:31-39 (“In a second variation, the lysed moiety-sample solution can be transferred to a vessel that enables the moiety-bound nucleic acid volume to be captured and the waste volume to be removed in a flow through manner, either against the pores of a filter or in the presence of a magnetic field. In the second variation, the microparticles with bound nucleic acids are retained in a filter zone or a magnetic field zone of the vessel, and the liquid portion is flowed into a "waste chamber."”) • Patent No. 9,382,532 at 8:48-55 (“In the variation of the first example, the microparticles of the moiety-bound nucleic acid volume can be retained by a magnetic field within a portion of the fluidic pathway upon occlusion of the fluidic pathway at a suitable set of occlusion positions, and the wash solution can be delivered through the portion of the fluidic pathway and into a waste chamber of the cartridge to wash the microparticles with the bound target nucleic acid(s).”) • Patent No. 9,382,532 at 11:6-14 (“In a specific example of this variation, a system (such as the one described in U.S. patent application Ser. No. 13/766,359, entitled "System and Method for Processing and Detecting Nucleic Acids") can be used to aspirate the nucleic acid sample from a fluidic path way of a cartridge (such as the one described in U.S. patent application Ser. No. 13/765,996, entitled "Microfluidic Cartridge for Processing and Detecting Nucleic Acids"), while the microparticles are immobilized by a magnet.”) • Patent No. 9,382,532 at 13:42-14:2 (“A first example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, cerebrospinal fluid (CSF) as a representative biological sample, and Enterovirus (EV) viral particles as the model target. In the first example, 200 μL of CSF was spiked with 2 μL of EV viral particle lysate and then mixed with 500 μL of RNA Collection Buffer 1 (CBR-1) and 300 μL of nuclease-free water in examples of Steps S110 and S120. As a comparison, a similar amount of EV particle lysate was spiked into a 1 mL solution comprised of 500 μL of CBR-1 buffer and 500 μL of nuclease-free water and processed simultaneously. In an example of Step S130, RNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 60 C. Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice
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		<p>(2x) with 500 µL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160. Isolated RNA was eluted into 10 µL of EL U-2 and 8 µL of the eluate was used for real-time RT-PCR in an example of Step S170. As shown in FIG. 4, results of the RNA isolation as elucidated by a real-time Enterovirus RT-PCR assay indicate that the RNA isolation process is substantially equally efficient in the biological sample matrix as compared to a simple buffer sample. This indicates that the example method 100 and the nucleic acid isolation reagents are efficacious at capture, release and cleanup of the target RNA in CSF matrix in the first example.”)</p> <ul style="list-style-type: none"> • Patent No. 9,382,532 at 24:1-12 (“A first illustration of the eighteenth example, as shown in FIG. 22A, of a fluidic pathway 165 preferably comprises an initial segment 174 fluidically coupled to a fluid channel 119 coupled to a shared fluid port 118, a sample segment 175 coupled to a sample port 114 and to the initial segment 174, and an s-shaped capture segment 166, configured to pass through the heating region 195 and a magnetic field 156, coupled to the initial segment 174 and the sample segment 175. In an alternative illustration of the eighteenth example, the s-shaped capture segment 166 may comprise an initial wide arc 166 to provide a greater surface area for magnetic bead capture.”) • Patent No. 9,382,532 at 24:65-25:2 (“Nucleic acids bound to magnetic beads may thus be trapped within the capture segment 166 by the magnetic field 156, while other substances in the volume of sample fluid may pass into the waste chamber 130 by passing the fifth occlusion position 146.”) <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> • Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly
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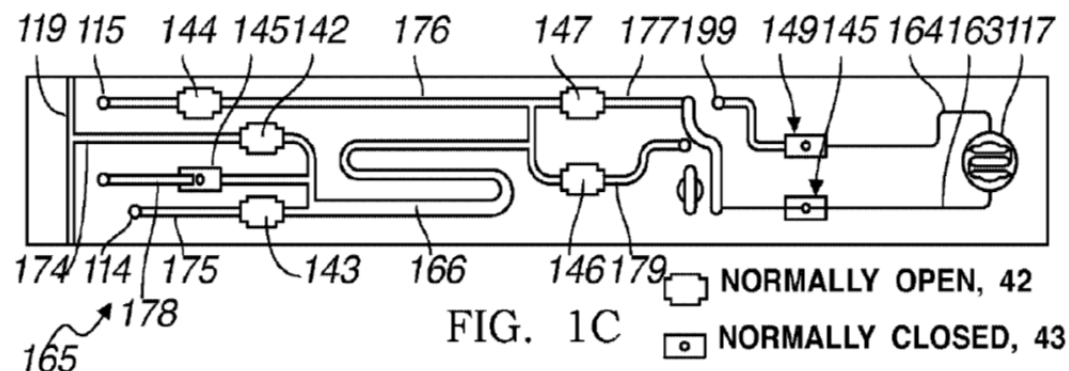
		<p>coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position of the fluidic pathway, by way of the void of the corrugated surface, the fluidic pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber.</p> <ul style="list-style-type: none"> • Claim 3. The cartridge of claim 1, wherein the waste chamber comprises at least one waste inlet in communication with the opening of the intermediate substrate, and wherein the corrugated surface of the waste chamber further defines a rectangular prismatic void spanning a long dimension of the cartridge that defines a magnet housing region configured to reversibly receive a magnet from the direction perpendicular to a broad face of the first layer, and configured to cross the fluidic pathway. • Claim 4. The cartridge of claim 3, wherein the fluidic pathway comprises a capture segment, downstream of the sample port and configured to cross the magnet housing region multiple times. • Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate. • Claim 15. The cartridge of claim 8, wherein at least one void of the set of voids defined by the corrugated surface of the waste chamber is a rectangular prismatic void spanning a long dimension of the cartridge and defining a magnet housing region configured to cross the first fluidic pathway and the second fluidic pathway. • U.S. Patent No. 9,403,165 at 2:39-63 (“As shown in FIGS. 1A-1C, an embodiment
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of a microfluidic cartridge 100 for processing and detecting nucleic acids comprises: a top layer 110 comprising a set of sample port-reagent port pairs 112 and a set of detection chambers 116; an intermediate substrate 120, coupled to the top layer 110 and partially separated from the top layer by a film layer 125, configured to form a waste chamber 130; an elastomeric layer 140 partially situated on the intermediate substrate 120; **a magnet housing region 150 accessible by a magnet 152 providing a magnetic field 156**; and a set of fluidic pathways 160, each formed by at least a portion of the top layer 110, a portion of the film layer 125, and a portion of the elastomeric layer 140. In other embodiments, the microfluidic cartridge 100 may further comprise a bottom layer 170 coupled to the intermediate substrate 120 and configured to seal the waste chamber 130. Furthermore, the top layer 110 of the microfluidic cartridge 100 may further comprise a shared fluid port 118, a vent region 190, and a heating region 195, such that each fluidic pathway 165 in the set of fluidic pathways 160 is fluidically coupled to a sample port-reagent port pair 113, the shared fluid port 118, the waste chamber 130, and a detection chamber 117, **comprises a capture segment 166 configured to pass through the heating region and the magnetic field**, and is configured to pass through the vent region 190 upstream of the detection chamber 117.”)

- U.S. Patent No. 9,403,165 at FIG. 1B



- U.S. Patent No. 9,403,165 at FIG. 1C.



- U.S. Patent No. 9,403,165 at 12:38-45 (“**The magnet housing region 150** of the microfluidic cartridge 100 functions to provide access to and/or house **at least one magnet 152 providing a magnetic field 156 for purification and isolation of nucleic acids**. Preferably, the magnet housing region 150 is defined by the film layer and the intermediate substrate, such that the film layer and the intermediate substrate form the boundaries of the magnet housing region 150.”)
- U.S. Patent No. 9,403,165 16:58-17:5 (“As shown in FIG. 1H, the first and the fourth occlusion positions 142, 145 may then be occluded to form a sixth truncated pathway sealing the volume of release solution, **with the captured magnetic beads bound to nucleic acids, within the capture segment 166**. The volume of the remaining release solution is therefore substantially defined by the microchannel volume between junctions in the fluidic pathway 165 near the fourth and sixth occlusion positions 145, 147, and may be any small volume but in a specific variation is precisely metered to be 23+/-1 microliters. Release solution may be sealed within capture segments of other fluidic pathways using a similar process. A heater may then be provided at the sixth truncated pathway, inducing a pH shift within the sixth truncated pathway **to unbind nucleic acids from the magnetic beads.**”)
- U.S. Patent No. 9,403,165 at 20:62-21:3 (“The first channel type 171 is preferably used over a majority of a fluidic pathway 165, and preferably in portions near a vent region 190, in a capture segment 166 configured to pass through a magnetic field 156, and in a segment leading to a Detection chamber 163. Preferably, an

		<p>embodiment of the first channel type 171, comprising a wide channel with little depth is used in regions configured to pass through a magnetic field 156, such that particles in the regions are driven closer to the magnetic field source.")</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,403,165 at 21:17-32 ("Multiple fluidic pathways may be configured to pass through a single heating region 195 of the microfluidic cartridge 100, a single vent region 190 of the microfluidic cartridge 100, and/or a magnetic field 156 produced by a magnet 152 housed within a single magnet housing region 150. Preferably all fluidic pathways of the set of fluidic pathways 160 are configured to pass through a single heating region 195 of the microfluidic cartridge 100, a single vent region 190 of the microfluidic cartridge 100, and a magnetic field 156 produced by a magnet 152 housed within a single magnet housing region 150; however, alternative embodiments of the set of fluidic pathways 160 of the microfluidic cartridge may comprise different configurations wherein fluidic pathways of the set of fluidic pathways 160 do not share a single heating region 195, a single vent region 190, and/or a magnetic field 156.") <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 8. The system of claim 1, wherein the magnet is configured to provide a
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		<p>magnetic field spanning at least three fluidic pathways configured to facilitate isolation and extraction of three nucleic acid volumes.</p> <ul style="list-style-type: none"> • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module. • Claim 23. A system for processing and detecting nucleic acids, comprising: a molecular diagnostic module, configured to process a set of biological samples combined with magnetic beads and separate a set of nucleic acid volumes from the set of biological samples combined with magnetic beads, wherein the molecular diagnostic module comprises an actuator configured to displace a cartridge, a set of pins, and at least one cam contacting the set of pins, wherein an
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		<p>extension or retraction of the actuator moves the cartridge, and a displacement of a subset of the set of pins defines a set of pathways in the cartridge, each configured to receive a biological sample combined with magnetic beads of the set of biological samples combined with magnetic beads.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) • U.S. Patent No. 9,050,594 at 7:63-8:6 (“As shown in FIGS. 7A-7C, the cartridge platform 141 is preferably configured to receive a microfluidic cartridge 210 along a cartridge loading guiderail 142 until it reaches a cartridge stop 143, and be vertically displaced by the linear actuator 146, which places a biasing force against the set of springs 148 coupled to the cartridge platform 141. The magnet receiving slot 144 and the set of valve actuation slots 145 provide access, by a magnet 160 and a valve actuation subsystem 170, to the microfluidic cartridge 210, as the microfluidic cartridge is vertically displaced by the linear actuator 146.”) • U.S. Patent No. 9,050,594 at FIG. 7A
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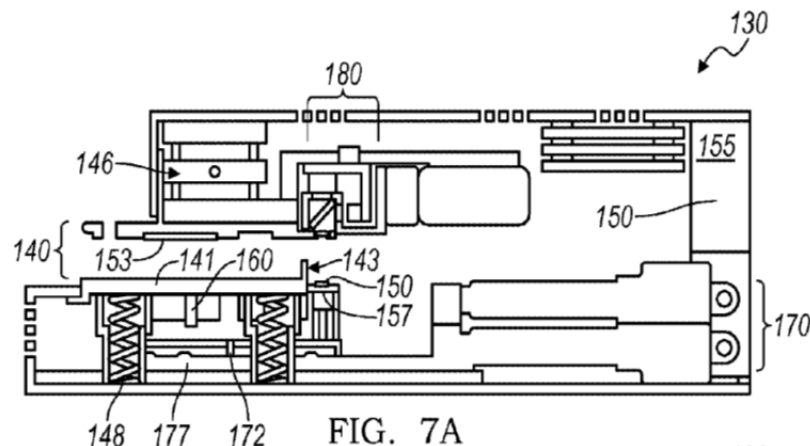


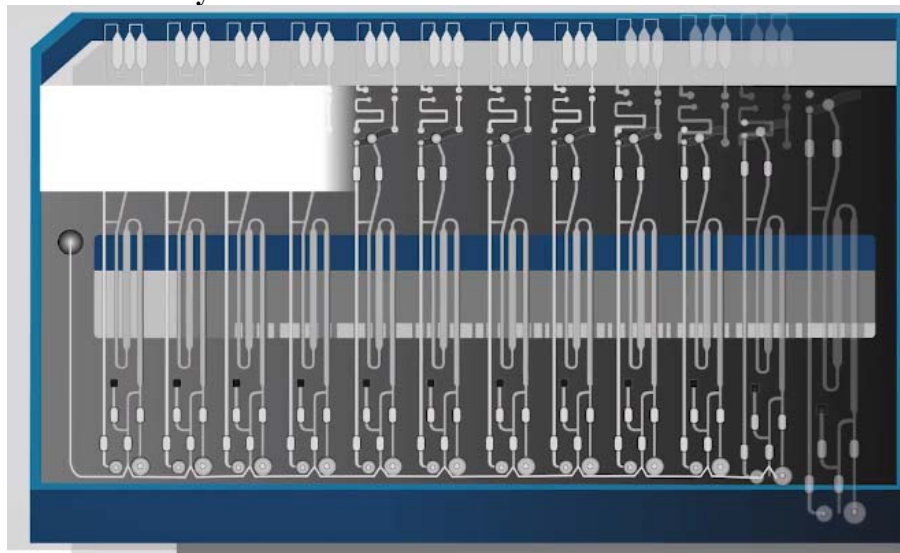
FIG. 7A

- U.S. Patent No. 9,050,594 at 12:64-13:16 (“**The magnet 160 of the molecular diagnostic module 130 functions to provide a magnetic field for isolation and extraction of nucleic acids bound to magnetic beads within a microfluidic cartridge 210, aligned within the molecular diagnostic module 130. Preferably, the magnet 160 is fixed within the molecular diagnostic module 130, such that the extended configuration 146 b of the linear actuator 146 allows the magnet 160 to pass through the magnet receiving slot 144 of the cartridge receiving module 140 and into a magnet housing region 218 of the microfluidic cartridge 210. In an example, as shown in FIGS. 7A-7C, the magnet 160 is a rectangular prism-shaped magnet 160 fixed under the cartridge platform 141, and configured to pass through the cartridge platform 141, into a magnet housing region 218 located under the heating region 224 of the microfluidic cartridge 210. Preferably, the magnet 160 is one of two or three magnets lined up in parallel, such that each of the fluidic pathways of a microfluidic cartridge housing the magnets is exposed to two or three times as much magnetic flux, and two to threes [sic] times as many opportunities to capture magnetic beads.**”)
- U.S. Patent No. 9,050,594 at 22:61-23:26 (“The microfluidic cartridge 210 is preferably configured to be received and manipulated by the molecular diagnostic module 130, such that the cartridge receiving module 140 of the molecular diagnostic module 130 receives and aligns the microfluidic cartridge 210 within the

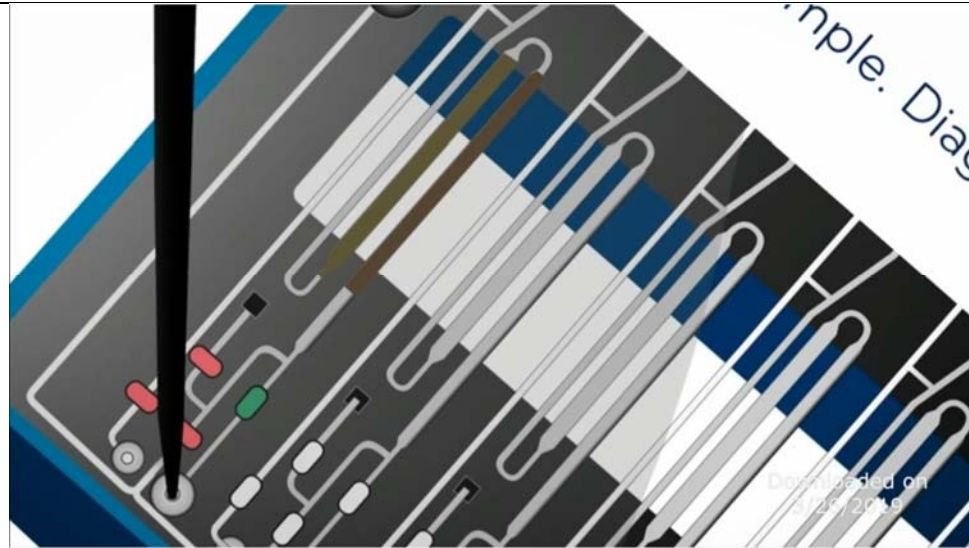
		<p>molecular diagnostic module 130, the heating and cooling subsystem 150 of the molecular diagnostic module 130 is configured to transfer heat to the heating region 224 of the microfluidic cartridge 210, and the magnet 160 of the molecular diagnostic module 130 is configured to be received by the magnet housing region 218 of the microfluidic cartridge 210 to provide a magnetic field for separation of nucleic acids.")</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 29:5-11 ("Step S430 may further comprise occluding at least one fluidic pathway of the set of fluidic pathways at a subset of a set of occlusion positions S432, which functions to define at least one truncated fluidic pathway. Preferably, Step S432 comprises defining at least one truncated fluidic pathway passing through at least one of a heating region and a magnetic field;") • U.S. Patent No. 9,050,594 at 29:27-40 ("Step S440 recites producing a set of nucleic acid volumes from the set of nucleic acid-magnetic bead samples, and functions to separate nucleic acid volumes from the set of nucleic acid-magnetic bead samples. Step S440 preferably reduces a concentration of unwanted matter from the set of biological samples being processed, to an acceptable level; however, Step S440 may alternatively entirely remove substantially all unwanted substances from the set of biological samples being processed. Step S440 preferably includes providing a magnetic field S441, such that each fluidic pathway in the set of fluidic pathways is configured to cross the magnetic field. Preferably, the set of nucleic acid-magnetic bead samples is captured and isolated within portions of the set of fluidic pathways crossing the magnetic field.")
1(h)	the magnetic separator comprising one or more magnets aligned along a second axis parallel to the first axis when the housing is received in the bay,	<p>In the accused system, the first module further comprises a magnetic separator positioned to apply a magnetic force to a first side of the plurality of process chambers when the housing is received in the bay, the magnetic separator comprising one or more magnets aligned along a second axis parallel to the first axis when the housing is received in the bay.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to "VIDEO NeuMoDx™</p>

WORKFLOW” hyperlink at <https://player.vimeo.com/video/299307936>. (Exhibit 16)

- “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains **12 independent lanes which allows for processing of up to 12 samples simultaneously.**” *Id.* at 1:49-1:59



- “Once the crude lysate is dispensed, a series of valves **directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel,** with the excess solution flowing into a self-contained waste chamber.” *Id.* at 2:28-2:39.
- *Id.* at 2:28 (showing lysate in the s-channel).



On information and belief, in the accused system, the first module further comprises a magnetic separator positioned to apply a magnetic force to a first side of the plurality of process chambers when the housing is received in the bay, the magnetic separator comprising one or more magnets aligned along a second axis parallel to the first axis when the housing is received in the bay.

US9382532 (Exhibit 52)

- Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a

		<p>cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 10. The method of claim 3, wherein washing the set of moiety-bound nucleic acid particles comprises aspirating the moiety-sample mixture; receiving the cartridge at the cartridge receiving module comprising the set of pins and a cam card interfacing with the set of pins; transitioning the cartridge to an active configuration that disposes the cartridge proximal the set of pins; displacing the first subset of the set of pins in the active configuration of the cartridge, upon translation of the cam card relative to the set of pins, thereby occluding the fluidic pathway of the cartridge at a set of occlusion positions; delivering the moiety-sample mixture into the fluidic pathway, wherein the fluidic pathway is configured to pass through a magnetic field and is coupled to a waste chamber, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field; and delivering a wash solution through the fluidic pathway and into the waste chamber in a continuous flow operation.. • Claim 13. The method of claim 3, wherein releasing the nucleic acid sample from the set of moiety-bound nucleic acid particles comprises occluding the fluidic pathway of the cartridge, comprising the process chamber, at a set of occlusion positions, upon displacement of pins of the set of pins, to define a path through a magnetic field; delivering the set of moiety-bound nucleic acid particles into the path of the fluidic pathway; and delivering an elution solution into the fluidic pathway, thereby inducing a pH shift configured to release the nucleic acid sample from the set of moiety-bound nucleic acid particles.
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		<ul style="list-style-type: none"> • Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second subset of the set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction. • Claim 18. The method of claim 17, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety-sample mixture from the process chamber; occluding the fluidic pathway of the cartridge at a set of occlusion positions upon displacement of the first subset of the set of pins to generate a path through a magnetic field, and to a waste chamber of the cartridge; and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber. • Patent No. 9,382,532 at 8:48-55 (“In the variation of the first example, the microparticles of the moiety-bound nucleic acid volume can be retained by a
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		<p>magnetic field within a portion of the fluidic pathway upon occlusion of the fluidic pathway at a suitable set of occlusion positions, and the wash solution can be delivered through the portion of the fluidic pathway and into a waste chamber of the cartridge to wash the microparticles with the bound target nucleic acid(s).”)</p> <ul style="list-style-type: none"> • Patent No. 9,382,532 at 10:3-13 (“In the variation of the specific example, the microparticles of the moiety-bound nucleic acid volume can be retained by a magnetic field within a portion of the fluidic pathway upon occlusion of the fluidic pathway at a suitable set of occlusion positions, and the elution solution can be delivered through the portion of the fluidic pathway enable release of the nucleic acid sample from the microparticle. Additionally, a heating element of the system can be moved proximal to the portion of the fluidic pathway with the elution solution and the microparticles to further enhance release of the nucleic acid sample.”) • Patent No. 9,382,532 at 11:6-14 (“In a specific example of this variation, a system (such as the one described in U.S. patent application Ser. No. 13/766,359, entitled "System and Method for Processing and Detecting Nucleic Acids") can be used to aspirate the nucleic acid sample from a fluidic pathway of a cartridge (such as the one described in U.S. patent application Ser. No. 13/765,996, entitled "Microfluidic Cartridge for Processing and Detecting Nucleic Acids"), while the microparticles are immobilized by a magnet.”) <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> • Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position of the fluidic pathway, by way of the void of the corrugated surface, the fluidic pathway is configured to transfer waste
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		<p>fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber.</p> <ul style="list-style-type: none"> • Claim 3. The cartridge of claim 1, wherein the waste chamber comprises at least one waste inlet in communication with the opening of the intermediate substrate, and wherein the corrugated surface of the waste chamber further defines a rectangular prismatic void spanning a long dimension of the cartridge that defines a magnet housing region configured to reversibly receive a magnet from the direction perpendicular to a broad face of the first layer, and configured to cross the fluidic pathway. • Claim 4. The cartridge of claim 3, wherein the fluidic pathway comprises a capture segment, downstream of the sample port and configured to cross the magnet housing region multiple times. • Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate. • Claim 15. The cartridge of claim 8, wherein at least one void of the set of voids defined by the corrugated surface of the waste chamber is a rectangular prismatic void spanning a long dimension of the cartridge and defining a magnet housing region configured to cross the first fluidic pathway and the second fluidic pathway. • U.S. Patent No. 9,403,165 at 2:39-63 (“As shown in FIGS. 1A-1C, an embodiment of a microfluidic cartridge 100 for processing and detecting nucleic acids comprises: a top layer 110 comprising a set of sample port-reagent port pairs 112 and a set of detection chambers 116; an intermediate substrate 120, coupled to the
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		<p>top layer 110 and partially separated from the top layer by a film layer 125, configured to form a waste chamber 130; an elastomeric layer 140 partially situated on the intermediate substrate 120; a magnet housing region 150 accessible by a magnet 152 providing a magnetic field 156; and a set of fluidic pathways 160, each formed by at least a portion of the top layer 110, a portion of the film layer 125, and a portion of the elastomeric layer 140. In other embodiments, the microfluidic cartridge 100 may further comprise a bottom layer 170 coupled to the intermediate substrate 120 and configured to seal the waste chamber 130. Furthermore, the top layer 110 of the microfluidic cartridge 100 may further comprise a shared fluid port 118, a vent region 190, and a heating region 195, such that each fluidic pathway 165 in the set of fluidic pathways 160 is fluidically coupled to a sample port-reagent port pair 113, the shared fluid port 118, the waste chamber 130, and a detection chamber 117, comprises a capture segment 166 configured to pass through the heating region and the magnetic field, and is configured to pass through the vent region 190 upstream of the detection chamber 117.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,403,165 at 12:38-52 (“The magnet housing region 150 of the microfluidic cartridge 100 functions to provide access to and/or house at least one magnet 152 providing a magnetic field 156 for purification and isolation of nucleic acids. Preferably, the magnet housing region 150 is defined by the film layer and the intermediate substrate, such that the film layer and the intermediate substrate form the boundaries of the magnet housing region 150. In an embodiment of the microfluidic cartridge 100 comprising a bottom layer 170, the magnet housing region 150 may further be defined by the bottom layer 170, such that the bottom layer partially forms a boundary of the magnet housing region 150. The magnet housing region 150 is preferably a rectangular prism-shaped void in the microfluidic cartridge 150, and accessible only through one side of the microfluidic cartridge 100, as shown in FIG. 1B.”) • U.S. Patent No. 9,403,165 at 12:59-13:2 (“Preferably, the magnet housing region 150 is bounded on at least two sides by the waste chamber 130, and positioned near the middle of the microfluidic cartridge 100, such that a fluidic pathway 165 passing through the magnetic field 156 passes through the magnetic field 156 at least at one point along an intermediate portion of the fluidic pathway 165.”)
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		<p>Preferably, the magnet housing region 150 also substantially spans at least one dimension of the microfluidic cartridge, such that multiple fluidic pathways 165 of the microfluidic cartridge 100 cross the same magnet housing region 150, magnet 152, and/or magnetic field 156.")</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,403,165 at 21:17-32 ("Multiple fluidic pathways may be configured to pass through a single heating region 195 of the microfluidic cartridge 100, a single vent region 190 of the microfluidic cartridge 100, and/or a magnetic field 156 produced by a magnet 152 housed within a single magnet housing region 150. Preferably all fluidic pathways of the set of fluidic pathways 160 are configured to pass through a single heating region 195 of the microfluidic cartridge 100, a single vent region 190 of the microfluidic cartridge 100, and a magnetic field 156 produced by a magnet 152 housed within a single magnet housing region 150; however, alternative embodiments of the set of fluidic pathways 160 of the microfluidic cartridge may comprise different configurations wherein fluidic pathways of the set of fluidic pathways 160 do not share a single heating region 195, a single vent region 190, and/or a magnetic field 156.") <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.
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		<ul style="list-style-type: none"> • Claim 7. The system of claim 1, wherein a retracted configuration of the actuator allows the magnet to retract from the magnet receiving slot. • Claim 8. The system of claim 1, wherein the magnet is configured to provide a magnetic field spanning at least three fluidic pathways configured to facilitate isolation and extraction of three nucleic acid volumes. • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) • U.S. Patent No. 9,050,594 at 2:49-58 (“As shown in FIGS. 1A-1B and 7A, an embodiment of a system 100 for processing and detecting nucleic acids comprises: a capture plate 110 configured to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119; a molecular diagnostic module 130 comprising a microfluidic cartridge receiving module 140, heating and cooling subsystem 150, a magnet 160, a valve actuation subsystem 170, an optical subsystem 180; and an assay strip 190 configured to facilitate mixing of molecular
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diagnostic reagents with a nucleic acid volume.”)

- U.S. Patent No. 9,050,594 at 7:63-8:6 (“As shown in FIGS. 7A-7C, the cartridge platform 141 is preferably configured to receive a microfluidic cartridge 210 along a cartridge loading guiderail 142 until it reaches a cartridge stop 143, and be vertically displaced by the linear actuator 146, which places a biasing force against the set of springs 148 coupled to the cartridge platform 141. **The magnet receiving slot 144 and the set of valve actuation slots 145 provide access, by a magnet 160 and a valve actuation subsystem 170, to the microfluidic cartridge 210, as the microfluidic cartridge is vertically displaced by the linear actuator 146.**”)
- U.S. Patent No. 9,050,594 at FIG. 7A

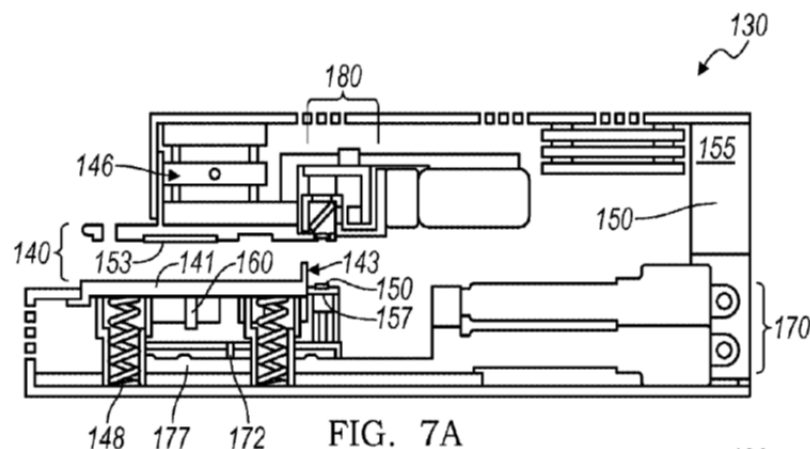


FIG. 7A

- U.S. Patent No. 9,050,594 at 8:36-53 (“The embodiment of the cartridge platform 141 shown in FIG. 8 also includes a set of valve actuation slots 145, oriented perpendicular to the parallel cartridge loading guiderails 142 and configured to provide access to a valve actuation subsystem 170, and **a magnet receiving slot 144 located among the set of valve actuation slots 145. Preferably, the magnet receiving slot 144 and the set of valve actuation slots 145 substantially span a long dimension of the cartridge platform 141, as shown in FIG. 8, and are configured to correspond to locations on a microfluidic cartridge 210 requiring a magnetic field and/or valving to enable processing of a biological sample and nucleic acid detection once the microfluidic cartridge 210 has been**

		<p>aligned within the molecular diagnostic module 130. Thus, alternative configurations of the magnet receiving slot 144 and the set of valve actuation slots 145 may accommodate other cartridges with alternative regions requiring magnetic fields and/or valving to enable other protocols.")</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 12:64-13:18 ("The magnet 160 of the molecular diagnostic module 130 functions to provide a magnetic field for isolation and extraction of nucleic acids bound to magnetic beads within a microfluidic cartridge 210, aligned within the molecular diagnostic module 130. Preferably, the magnet 160 is fixed within the molecular diagnostic module 130, such that the extended configuration 146 b of the linear actuator 146 allows the magnet 160 to pass through the magnet receiving slot 144 of the cartridge receiving module 140 and into a magnet housing region 218 of the microfluidic cartridge 210. In an example, as shown in FIGS. 7A-7C, the magnet 160 is a rectangular prism-shaped magnet 160 fixed under the cartridge platform 141, and configured to pass through the cartridge platform 141, into a magnet housing region 218 located under the heating region 224 of the microfluidic cartridge 210. Preferably, the magnet 160 is one of two or three magnets lined up in parallel, such that each of the fluidic pathways of a microfluidic cartridge housing the magnets is exposed to two or three times as much magnetic flux, and two to threes [sic] times as many opportunities to capture magnetic beads. Alternatively, the magnet 160 is a single magnet configured to expose a set of fluidic pathways to a magnetic field.") • U.S. Patent No. 9,050,594 at 13:26-43 ("In one variation, the magnet 160 or group of multiple magnets comprises a permanent magnet, composed of a magnetized material (e.g., a ferromagnet) providing a substantially fixed magnetic field. In an alternative variation, the magnet 160 or group of multiple magnets comprises an electromagnet configured to provide a modifiable magnetic field, such that the intensity of the magnetic field can be adjusted, the polarity of the magnetic field can be reversed, and the magnetic field can be substantially removed upon removal of a current flowing within the electromagnet. Preferably, the magnet 160 or group of magnets is also fixed relative to the molecular diagnostic module 130; however, the magnet 160 or group of magnets may alternatively be configured to translate vertically (in the orientation shown in FIG.
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		<p>7B), such that the magnet 160 or group of magnets can extend into and retract from the magnet receiving slot 144 of the cartridge platform 141 and the magnet housing region 218 of the microfluidic cartridge 210.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 22:61-23:5 (“The microfluidic cartridge 210 is preferably configured to be received and manipulated by the molecular diagnostic module 130, such that the cartridge receiving module 140 of the molecular diagnostic module 130 receives and aligns the microfluidic cartridge 210 within the molecular diagnostic module 130, the heating and cooling subsystem 150 of the molecular diagnostic module 130 is configured to transfer heat to the heating region 224 of the microfluidic cartridge 210, and the magnet 160 of the molecular diagnostic module 130 is configured to be received by the magnet housing region 218 of the microfluidic cartridge 210 to provide a magnetic field for separation of nucleic acids.”)
1(i)	the one or more complementary registration members further configured to align the plurality of process chambers with the magnetic separator when the housing is received in the bay, and	<p>In the accused system, the first module further comprises a magnetic separator positioned to apply a magnetic force to a first side of the plurality of process chambers when the housing is received in the bay, the magnetic separator comprising one or more magnets aligned along a second axis parallel to the first axis when the housing is received in the bay, the one or more complementary registration members further configured to align the plurality of process chambers with the magnetic separator when the housing is received in the bay.</p> <p><i>NeuMoDx Molecular N288 Overview and Animation</i>, http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ TECHNOLOGY” hyperlink at https://player.vimeo.com/video/281470603. (Exhibit 17)</p> <ul style="list-style-type: none"> At 4:17 (showing a plurality of multi-lane microfluidic cartridges in a plurality of receiving bays)



- at 4:55-5:00 (showing a plurality of multi-lane microfluidic cartridges in a plurality of receiving bays)





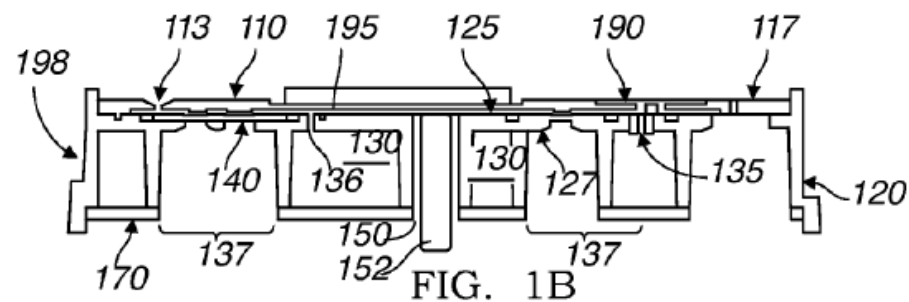
On information and belief, in the accused system the first module further comprises a magnetic separator positioned to apply a magnetic force to a first side of the plurality of process chambers when the housing is received in the bay, the magnetic separator comprising one or more magnets aligned along a second axis parallel to the first axis when the housing is received in the bay, the one or more complementary registration members further configured to align the plurality of process chambers with the magnetic separator when the housing is received in the bay.

US 9403165 (Exhibit 27)

- Claim 3. The cartridge of claim 1, wherein the waste chamber comprises at least one waste inlet in communication with the opening of the intermediate substrate, and wherein the **corrugated surface of the waste chamber further defines a rectangular prismatic void spanning a long dimension of the cartridge that defines a magnet housing region configured to reversibly receive a magnet from the direction perpendicular to a broad face of the first layer, and configured to cross the fluidic pathway.**
- US 9403165 at 12:52-58 (“Preferably, the magnet housing region 150 **can be reversibly passed over a magnet 152 to house the magnet 152, and retracted to remove the magnet from the magnet housing region 150;** however, the magnet 152 may alternatively be irreversibly fixed within the magnet housing region 150 once the magnet 152 enters the magnet housing region 150.”)
- Claim 15. “The cartridge of claim 8, wherein at least one void of the set of voids defined by the corrugated surface of the waste chamber is a rectangular prismatic void spanning a long dimension of the cartridge and defining a magnet housing

region configured to cross the first fluidic pathway and the second fluidic pathway.”

- US 9,403,165 at 2:39-51 (“As shown in FIGS. 1A-1C, an embodiment of a microfluidic cartridge 100 for processing and detecting nucleic acids comprises: a top layer 110 comprising a set of sample port reagent port pairs 112 and a set of detection chambers 116; an intermediate substrate 120, coupled to the top layer 110 and partially separated from the top layer by a film layer 125, configured to form a waste chamber 130; an elastomeric layer 140 partially situated on the intermediate substrate 120; a **magnet housing region 150 accessible by a magnet 152 providing a magnetic field 156**; and a set of fluidic pathways 160, each formed by at least a portion of the top layer 110, a portion of the film layer 125, and a portion of the elastomeric layer 140.”)
- US 9,403,165 at FIG. 1B



- US 9,403,165 at FIG. 6C

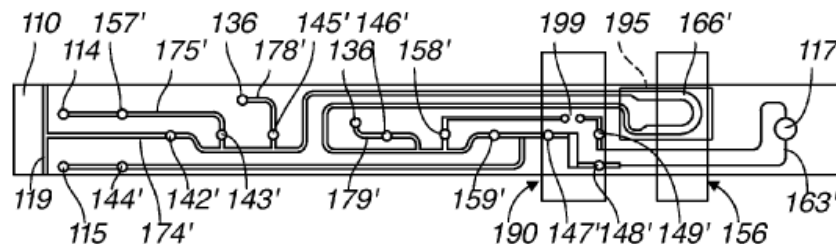


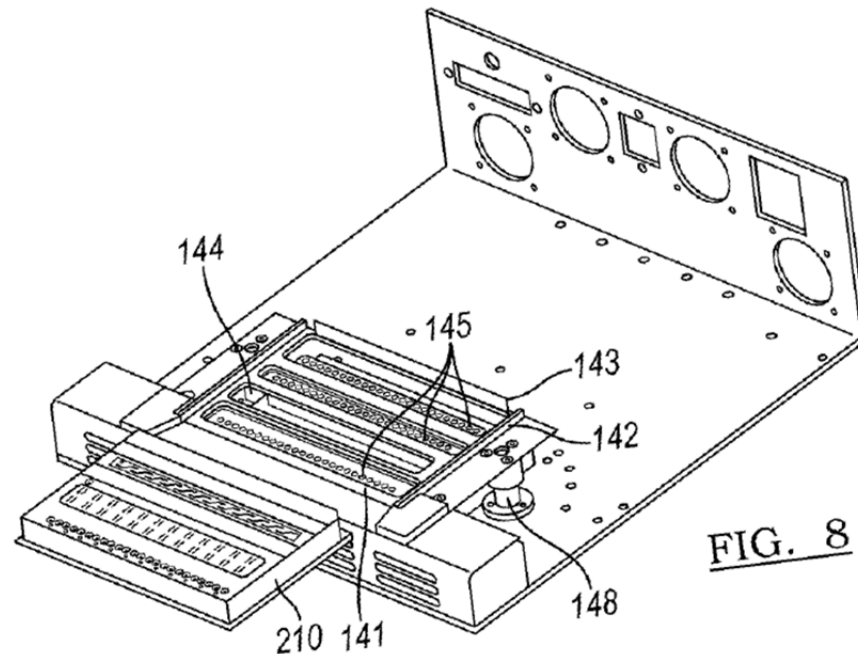
FIG. 6C

- US 9403165 at 12:59-13:6 (“Preferably, the magnet housing region 150 is bounded on at least two sides by the waste chamber 130, and **positioned near the middle of the microfluidic cartridge 100**, such that a fluidic pathway 165 passing through the magnetic field 156 passes through the magnetic field 156 at least at one point along an intermediate portion of the fluidic pathway 165. Preferably, the magnet housing region 150 also substantially spans at least one dimension of the microfluidic cartridge, such that multiple fluidic pathways 165 of the microfluidic cartridge 100 cross the same magnet housing region 150, magnet 152, and/or magnetic field 156. Alternatively, the magnet housing region 150 may be configured such that a magnet within the magnet housing region 150 provides a magnetic field spanning all fluidic pathways 165 of the microfluidic cartridge in their entirety.”)
- 9,403,165 at 22:42-55 (“The specific embodiment of the microfluidic cartridge 100 comprises a top layer 110 including a set of twelve sample port-reagent port pairs 112, a set of twelve detection chambers 116, a shared fluid port 118, a heating region 195, and a vent region 190, an intermediate substrate 120, coupled to the top layer 110 and partially separated from the top layer 110 by a film layer 125, configured to form a waste chamber 130, an elastomeric layer 140 partially situated on the intermediate substrate 120; **a magnet housing region 150 accessible by a magnet 152 providing a magnetic field 156**; a bottom layer 170 coupled to the intermediate substrate 120 and configured to seal the waste chamber, and a set of fluidic pathways 160, formed by at least a portion of the top layer 110, a portion of the film layer 125, and a portion of the elastomeric layer 140.”)

		<p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • U.S. Patent No. 9,050,594 at 7:53-8:6 (“As shown in FIG. 9A, the cartridge receiving module 140 of the molecular diagnostic module 130 comprises a cartridge platform 141 including a cartridge loading guiderail 142, a cartridge stop 143, a magnet receiving slot 144, and a set of valve actuation slots 145; a linear actuator 146 configured to displace a microfluidic cartridge 210 resting on the cartridge platform 141, and a set of springs 148 coupled to the cartridge platform 141. The cartridge receiving module 140 thus functions to receive, align, and compress a microfluidic cartridge 210 for processing of a biological sample according to a molecular diagnostic assay protocol. As shown in FIGS. 7A-7C, the
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		<p>cartridge platform 141 is preferably configured to receive a microfluidic cartridge 210 along a cartridge loading guiderail 142 until it reaches a cartridge stop 143, and be vertically displaced by the linear actuator 146, which places a biasing force against the set of springs 148 coupled to the cartridge platform 141. The magnet receiving slot 144 and the set of valve actuation slots 145 provide access, by a magnet 160 and a valve actuation subsystem 170, to the microfluidic cartridge 210, as the microfluidic cartridge is vertically displaced by the linear actuator 146.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 8:7-35 (“The cartridge platform 141 includes a cartridge loading guiderail 142, a cartridge stop 143, a magnet receiving slot 144, and a set of valve actuation slots 145, and functions to receive and align a microfluidic cartridge 210, while providing access to the microfluidic cartridge 210 by a magnet 160 and a valve actuation subsystem 170. As shown in FIG. 8, an embodiment of the cartridge platform 141 includes a pair of parallel cartridge loading guiderails 142, initiating at a pair of inwardly tapering protrusions configured to guide a microfluidic cartridge toward the pair of parallel cartridge loading guiderails 142, and spanning two short edges of the cartridge platform 141. The embodiment of the cartridge platform 141 also includes a cartridge stop 143 comprising a vertical tab oriented perpendicular to the cartridge loading guiderails 142, and spanning a long edge of the cartridge platform. Preferably, the cartridge loading guiderails 142 and the cartridge stop 143 are configured such that a microfluidic cartridge 210 slides between the cartridge loading guiderails 142 and hits the cartridge stop 143 to signal proper alignment. Alternatively, the cartridge loading guiderails 142 and the cartridge stop 143 may be configured such that a microfluidic cartridge slides over or along the cartridge loading guiderails 142, after which the cartridge stop 143 couples to a portion of the microfluidic cartridge 210 to ensure proper alignment of the microfluidic cartridge. Additional variations of the cartridge loading guiderails 142 and the cartridge stop 143 may be used to enable reception and alignment of a microfluidic cartridge 210 by the molecular diagnostic module 130, and are known by those skilled in the art.”) • U.S. Patent No. 9,050,594 at 8:36-59 (“The embodiment of the cartridge platform 141 shown in FIG. 8 also includes a set of valve actuation slots 145, oriented
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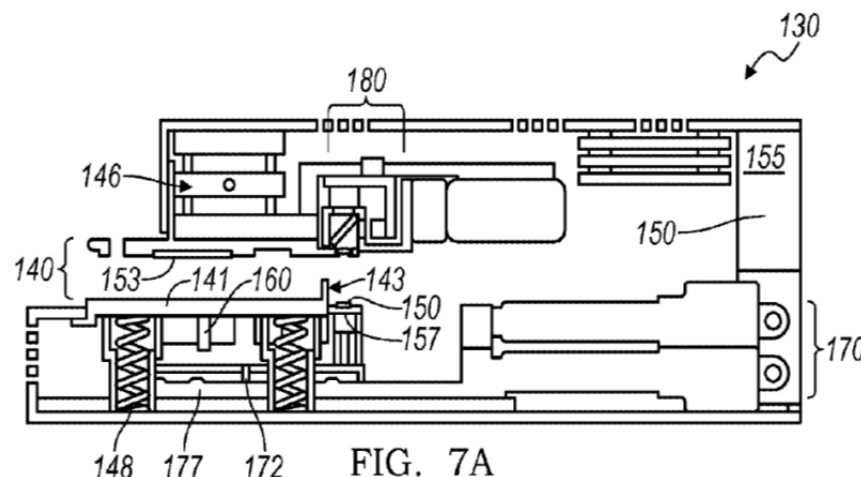
		<p>perpendicular to the parallel cartridge loading guiderails 142 and configured to provide access to a valve actuation subsystem 170, and a magnet receiving slot 144 located among the set of valve actuation slots 145. Preferably, the magnet receiving slot 144 and the set of valve actuation slots 145 substantially span a long dimension of the cartridge platform 141, as shown in FIG. 8, and are configured to correspond to locations on a microfluidic cartridge 210 requiring a magnetic field and/or valving to enable processing of a biological sample and nucleic acid detection once the microfluidic cartridge 210 has been aligned within the molecular diagnostic module 130. Thus, alternative configurations of the magnet receiving slot 144 and the set of valve actuation slots 145 may accommodate other cartridges with alternative regions requiring magnetic fields and/or valving to enable other protocols. In one alternative embodiment, the magnet receiving slot 144 and the set of valve actuation slots may comprise one continuous void of the cartridge platform 141, such that the cartridge platform 141 supports a microfluidic cartridge 210 along the periphery of the microfluidic cartridge 210, but forms a continuous void under a majority of the footprint of the microfluidic cartridge 210.”)</p> <ul style="list-style-type: none">• U.S. Patent No. 9,050,594 at FIG. 8.
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- U.S. Patent No. 9,050,594 at 10:5-26 (“Similarly, the nozzle 149, the heating and cooling subsystem 150, the cartridge heater 153, and the magnet 160 are preferably coupled to springs, such that springs are positioned between elements 149, 150, 153, and 160, and substrates that elements 149, 150, 153, and 160 are mounted to. Alternatively an elastomeric material is preferably positioned between elements 149, 150, 153, and 160, and substrates that elements 149, 150, 153, and 160 are mounted to. The springs and/or elastomeric material function to provide proper functioning and **alignment of subsystems of the molecular diagnostic module 130 as the linear actuator 146 is extended or retracted**, contributing to reliability and a reduction in stack up tolerance risk. The springs and/or elastomeric material further function to allow more pressure to be applied to occlusion positions of a microfluidic cartridge 210 aligned within the molecular diagnostic module 130, and an appropriate pressure to be applied to elements 149, 150, 153 and 160 of the molecular diagnostic module 130. **Thus, proper contact is maintained between elements 149, 150, 153, and 160, and a microfluidic**

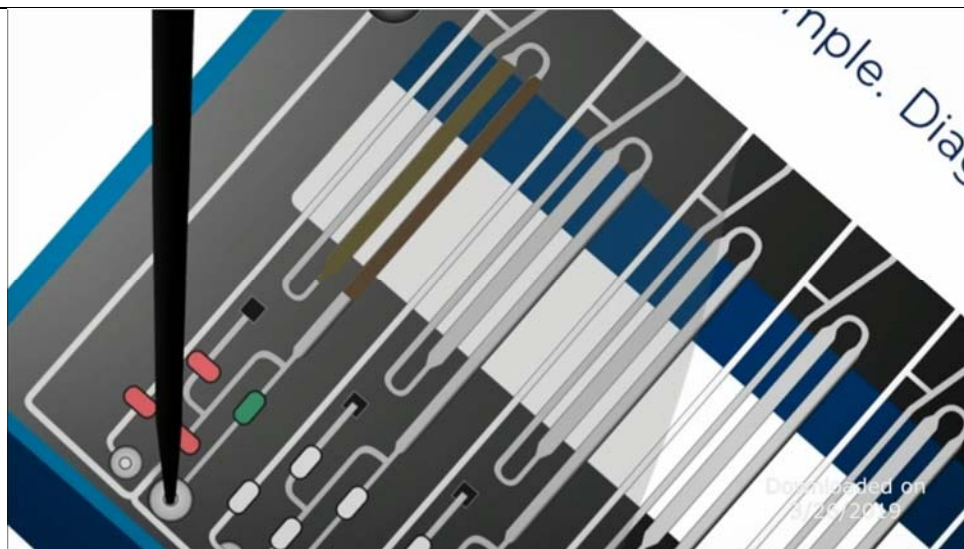
cartridge 210 being manipulated by the molecular diagnostic module. These elements are described in further detail below.”)

- U.S. Patent No. 9,050,594 at 7A.



- U.S. Patent No. 9,050,594 at 8:60-9:32 (“The linear actuator 146 functions to linearly displace a microfluidic cartridge 210 resting on the cartridge platform 141, in order to compress the microfluidic cartridge 210 and position the microfluidic cartridge 210 between a cartridge heater 153 and an optical subsystem 180 on one side of the microfluidic cartridge 210, and a magnet 160 and detection chamber heaters 157 on another side of the microfluidic cartridge 210. The linear actuator 146 also functions to provide a sufficient counterforce to the valve actuation subsystem 170 such that a microfluidic cartridge 210 within the molecular diagnostic module 130 remains properly situation upon manipulation by the valve actuation subsystem 170. The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210. In the orientation of the molecular diagnostic module 130 shown in FIGS. 7B and 7B, the linear actuator 146 is preferably coupled to a portion of the heating and cooling subsystem 150 a portion of the optical subsystem 180, and the nozzle 149, and vertically displaces the cartridge heater 153, the optical subsystem 180, and the nozzle 149 to position the cartridge heater 153, 180 and the nozzle 149 over the

		<p>microfluidic cartridge 210. The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR). Preferably, the linear actuator 146 is a scissor jack actuator configured to apply substantially uniform pressure over all occlusion positions of a microfluidic cartridge 210 aligned within the molecular diagnostic module 130, and to operate in at least two configurations. In a retracted configuration 146 a, as shown in FIG. 9A, the scissor jack actuator has not linearly displaced the cartridge platform 141, and in an extended configuration 146 b, as shown in FIG. 9B, the scissor jack actuator has linearly displaced the microfluidic cartridge 210 to position the microfluidic cartridge 210 between the subsystems 153, and 180, and the magnet 160 and detection chamber heaters 157.")</p>
1(j)	<p>the first module further comprising a heating assembly positioned adjacent to a second side of the plurality of process chambers opposite the first side when the housing is received in the bay,</p>	<p>In the accused system, the first module further comprises a heating assembly positioned adjacent to a second side of the plurality of process chambers opposite the first side when the housing is received in the bay. <i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to "VIDEO NeuMoDx™ WORKFLOW" hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • "Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber." <i>Id.</i> at 2:28-2:39. • <i>Id.</i> at 2:28 (showing lysate in the s-channel).



- “A precise volume of air is then applied to remove any remaining liquid into the waste chamber. NeuMoDx wash solution is pumped via the fluid port into the microfluidic cartridge to remove all unbound material, followed by another volume of air to remove excess wash solution. High pH NeuMoDx release reagent is dispensed into the s-channel to cover the beads, and **heat is applied to the denaturation process, resulting in released nucleic acid or eluate.**” *Id.* at 2:39-3:12.

On information and belief, in the accused system, the first module further comprises a heating assembly positioned adjacent to a second side of the plurality of process chambers opposite the first side when the housing is received in the bay.

US9403165 (Exhibit 27)

- Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the

		<p>waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate.</p> <ul style="list-style-type: none"> • Claim 11. The cartridge of claim 10, further comprising 1) a heating region defined as a recessed region of the first layer that is parallel to the set of voids of the corrugated surface, and 2) a vent region, such that the first fluidic pathway is configured to cross the heating region and to pass through the vent region upstream of the first detection chamber, and the second fluidic pathway is configured to cross the heating region and to pass through the vent region upstream of the second detection chamber. • U.S. Patent No. 9,403,165 at 3:27-32 (“As shown in FIGS. 1B and 1C, the top layer 110 preferably comprises a set of sample port-reagent port pairs 112, a fluid port 118, a vent region 190, a heating region 195 crossing a capture segment 166 of a fluidic pathway 165, and a set of detection chambers 116.”) • U.S. Patent No. 9,403,165 at 1A.
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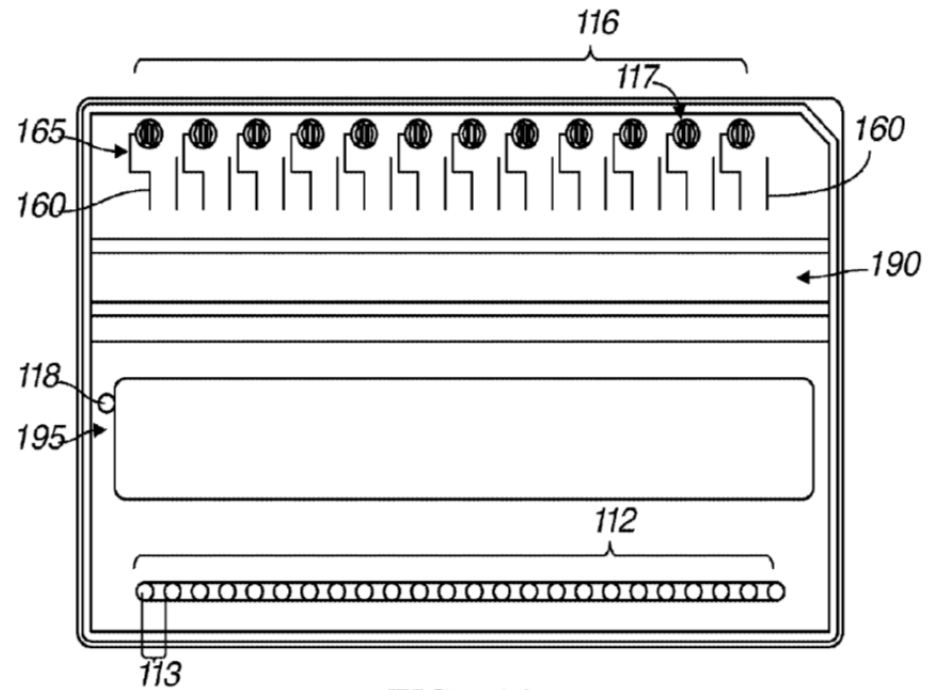


FIG. 1A

- U.S. Patent No. 9,403,165 at FIG. 1B

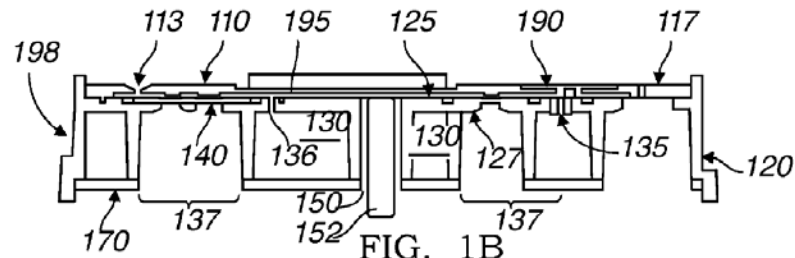
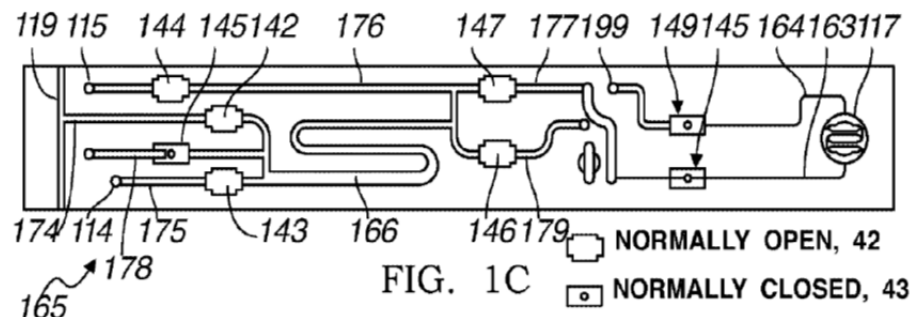


FIG. 1B

- U.S. Patent No. 9,403,165 at FIG. 1C .



- U.S. Patent No. 9,403,165 at 13:40-47 (“Furthermore, at least one fluidic pathway 165 in the set of fluidic pathways 160 is preferably configured to be occluded upon deformation of the elastomeric layer 140, configured to transfer a waste fluid to the waste chamber 30, **comprises a capture segment 166 passing through the heating region 195 and a magnetic field 156**, and is configured to pass through the vent region 190 upstream of a detection chamber 117.”)
- U.S. Patent No. 9,403,165 at 14:39-50 (“As shown in FIGS. 1C, 6C, 7 and 9, a fluidic pathway 165 of the set of fluidic pathways 160 is branched and preferably comprises an initial segment 174 fluidically coupled to a fluid channel 119 coupled to a fluid port 118, a sample segment 175 coupled to a sample port 114, a reagent segment 176 coupled to a reagent port 115, **a capture segment 166 passing through at least one of the heating region 195 and a magnetic field 156**, a vent segment 177 configured to pass through the vent region 190, a segment running to a detection chamber 163, a segment running away from the detection chamber 164, and at least one waste segment 178, 179 configured to transfer a waste fluid to a waste chamber 130.”)
- U.S. Patent No. 9,403,165 at 16:58-17:5 (“As shown in FIG. 1H, the first and the fourth occlusion positions 142, 145 may then be occluded to form a sixth truncated pathway sealing the volume of release solution, with the captured magnetic beads bound to nucleic acids, within the capture segment 166. The volume of the remaining release solution is therefore substantially defined by the microchannel volume between junctions in the fluidic pathway 165 near the fourth and sixth occlusion positions 145, 147, and may be any small volume but in a specific variation is precisely metered to be 23+/-1 microliters. Release solution may be

		<p>sealed within capture segments of other fluidic pathways using a similar process. A heater may then be provided at the sixth truncated pathway, inducing a pH shift within the sixth truncated pathway to unbind nucleic acids from the magnetic beads.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at 21:17-32 (“Multiple fluidic pathways may be configured to pass through a single heating region 195 of the microfluidic cartridge 100, a single vent region 190 of the microfluidic cartridge 100, and/or a magnetic field 156 produced by a magnet 152 housed within a single magnet housing region 150. Preferably all fluidic pathways of the set of fluidic pathways 160 are configured to pass through a single heating region 195 of the microfluidic cartridge 100, a single vent region 190 of the microfluidic cartridge 100, and a magnetic field 156 produced by a magnet 152 housed within a single magnet housing region 150; however, alternative embodiments of the set of fluidic pathways 160 of the microfluidic cartridge may comprise different configurations wherein fluidic pathways of the set of fluidic pathways 160 do not share a single heating region 195, a single vent region 190, and/or a magnetic field 156.”) <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-
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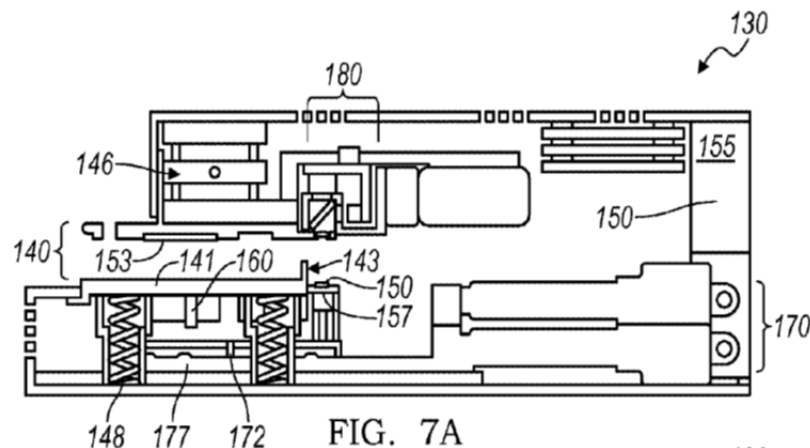
		<p>bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Patent No. 9,382,532 at 9:31-49 (“In some variations, Step S160 can further comprise Step S161, which recites heating the moiety-bound nucleic acid volume. Step S161 functions to provide additional environmental conditions that facilitate release of the nucleic acid sample from the microparticles, and can further function to mitigate effects of proteolytic enzymes that are used in Steps S110, S120, and/or S130 or that may be released from the biological sample containing the nucleic acid. Preferably, an elevated temperature in combination with an elevated pH resulting from the elution solution provides the enhanced conditions to facilitate the release of the nucleic acid sample. Furthermore, an elevated temperature (e.g., elevating a sample eluted at room temperature to 85 C) can function to minimize protease enzyme activity in the eluted nucleic acid and thereby improve the robustness of the detection of the target nucleic acid sample during processing in variations of Step S110; however, the method 100 can alternatively omit Step S161 in applications wherein heating the moiety-bound nucleic acid volume is undesirable and/or unnecessary.”) • Patent No. 9,382,532 at 13:42-60 (“A first example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, cerebrospinal fluid (CSF) as a representative biological sample, and Enterovirus (EV) viral particles as the model target. In the first example, 200 μL of CSF was spiked with 2 μL of EV viral particle lysate and then mixed with 500 μL of RNA Collection Buffer 1 (CBR-1) and 300 μL of nuclease-free water in examples of Steps S110 and S120. As a comparison, a similar amount of EV particle lysate was spiked into a 1 mL solution comprised of 500 μL of CBR-1 buffer and 500 μL of nuclease-free water and processed simultaneously. In an example of Step S130, RNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 60 C. Upon removal of the unbound supernatant in an example of
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		<p>Step S140, the magnetic microparticles with bound RNA were washed twice (2×) with 500 µL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) <i>See also id.</i> at 14:5-23, 14:41-59, 15:8-24, 15:58-6:12, 16:29-44, 16:61-16:10, 17:27-43, 17:60-18:14, 18:31-47, 19:12-27, 19:46-61, 20:7-23, 20:33-50, 21:23-39, 21:59-22:8, 22:31-49.</p> <ul style="list-style-type: none"> • Patent No. 9,382,532 at 15:36-55 (“In other variations of the first through fourth examples involving RNA extractions, the example method 100 can comprise any suitable combination of: adding guanidine to an RNA lysis buffer (e.g., 50 mM GuSCN), adding guanidine to a swab extraction buffer (e.g., 2M GuHCL, 2.5M GuHCL), providing any suitable lysis buffer (e.g., 50 mM TRIS pH 7 with 1 % Triton X, 50 mM EDTA, and 2M GuHCL; 1 mM Tris pH 8 in 1% Triton X and 100 mM EDTA), binding RNA to affinity moiety-coated microparticles at any suitable temperature (e.g., 37-60 C for up to 10 minutes), using any suitable amount (e.g., 7 .5 ug) of tRNA during lysis, using fresh or frozen samples, providing any suitable wash conditions (e.g, 1x salt wash, 1x salt wash+1x 1 mM TRIS pH 8 wash), providing any suitable binding conditions (e.g., 2x 1 mM TRIS pH 8 binding at 37 C, 2x 1 mM TRIS pH 8 at 60 C), eluting with any suitable elution conditions (e.g., room temperature to 85 C, 1 minute-10 minutes), providing any suitable composition of an elution solution (e.g., 20 mM Na OH, 40 mM Na OH, KOH), and using any suitable PCR mix for EV extractions.”) • Patent No. 9,382,532 at 24:1-12 (“A first illustration of the eighteenth example, as shown in FIG. 22A, of a fluidic pathway 165 preferably comprises an initial segment 174 fluidically coupled to a fluid channel 119 coupled to a shared fluid port 118, a sample segment 175 coupled to a sample port 114 and to the initial segment 174, and an s-shaped capture segment 166, configured to pass through the heating region 195 and a magnetic field 156, coupled to the initial segment 17 4 and the sample segment 175. In an alternative illustration of the eighteenth example, the s-shaped capture segment 166 may comprise an initial wide arc 166 to provide a greater surface area for magnetic bead capture.”) • Patent No. 9,382,532 at 25:47-50 (“A heater may then be provided at the sixth truncated pathway, inducing a pH shift within the sixth truncated pathway to unbind nucleic acids from the magnetic beads.”)
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		<p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 12. The system of claim 1, wherein the molecular diagnostic module further comprises a molecular diagnostic module heater configured to heat at least one magnetic bead-sample. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to
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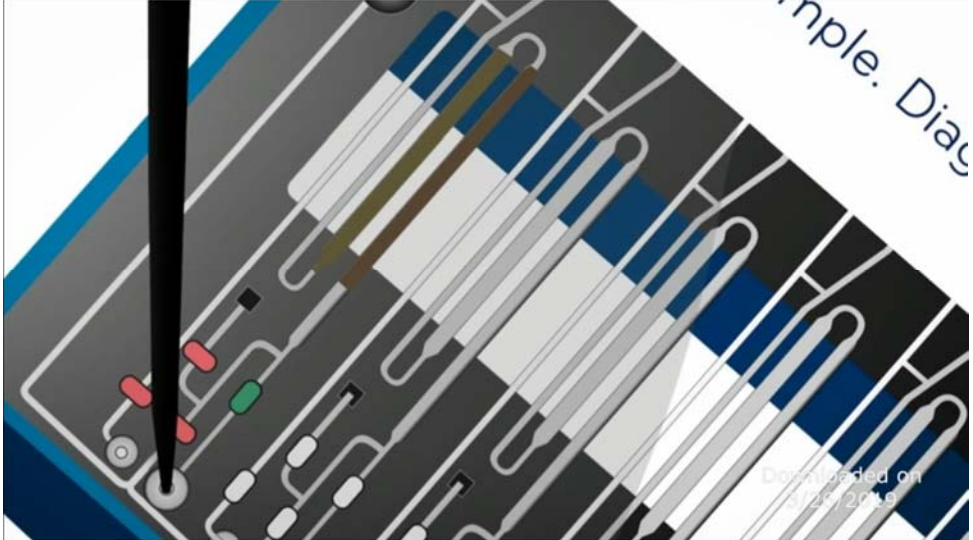
		<p>the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) • U.S. Patent No. 9,050,594 at 10:29-43 (“The heating and cooling subsystem 150 of the molecular diagnostic module 130 comprises a cartridge heater 153, a fan 155, and a set of detection chamber heaters 157 and functions to controllably heat portions of a microfluidic cartridge 210 for processing of a biological sample containing nucleic acids according to a molecular diagnostic protocol. In the orientation of an embodiment of the molecular diagnostic module 130 shown in FIGS. 7A-7C, the cartridge heater 153 is preferably coupled to the linear actuator 146 of the cartridge receiving module 140 and configured to span a central region of a microfluidic cartridge 210 aligned within the molecular diagnostic module 130, the fan 155 is located at a back wall of the cartridge receiving module 140, and the set of detection chamber heaters 157 is located
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- inferior to a set of detection chambers 213 of the microfluidic cartridge 210.”)
- U.S. Patent No. 9,050,594 at FIG. 7A



- U.S. Patent No. 9,050,594 at 10:49-56 (“The cartridge heater 153 functions to transfer heat to a heating region 224 of a microfluidic cartridge 210, for inducing a pH shift to release bound nucleic acids from magnetic beads within the heating region 224. The cartridge heater 153 is preferably a plate-shaped heater configured to transfer heat to the microfluidic cartridge 210 only from one side of the cartridge heater 153, such that heat flows through one face of the plate-shaped heater to the microfluidic cartridge 210.”)
- U.S. Patent No. 9,050,594 at 11:13-32 (“Preferably, the cartridge heater 153 is configured to linearly translate with the linear actuator 146 of the cartridge receiving module 140, in order to align with a heating region 224 spanning a central portion of a microfluidic cartridge 210 aligned within the molecular diagnostic module 130. In one variation, the cartridge heater 153 is preferably fixed relative to the linear actuator 146 such that (in the orientation shown in FIGS. 7B-7C), the cartridge heater 153 can only move vertically with the linear actuator. In an alternative variation, the cartridge heater 153 may additionally be configured to translate laterally with a horizontal plane (in the orientation shown in FIGS. 7B-7C), such that the cartridge heater 153 can translate in at least two perpendicular

		<p>coordinate planes. In this alternative variation, the cartridge heater 153 can be configured to sweep across a surface of a microfluidic cartridge 210 aligned within the molecular diagnostic module 130, or to translate in response to motion of the microfluidic cartridge 210, such that the position of the cartridge heater 153 relative to a heating region 224 of the microfluidic cartridge 210 is always fixed.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 22:47-60 (“Furthermore, in the embodiment, the top layer 211 of the microfluidic cartridge 210 further comprises a shared fluid port 222, a vent region 223, and a heating region 224, such that each fluidic pathway 220 in the set of fluidic pathways 219 is fluidically coupled to a sample port-reagent port pair 224, the shared fluid port 222, the waste chamber 216, and a detection chamber 225, comprises a turnabout portion 226 configured to pass through the heating region 224 and the magnetic field, and is configured to pass through the vent region 223 upstream of the detection chamber 225. Each fluidic pathway 220 thus functions to receive and facilitate processing of a sample fluid containing nucleic acids as it passes through different portions of the fluidic pathway 220.”) • U.S. Patent No. 9,050,594 at 22:61-23:5 (“The microfluidic cartridge 210 is preferably configured to be received and manipulated by the molecular diagnostic module 130, such that the cartridge receiving module 140 of the molecular diagnostic module 130 receives and aligns the microfluidic cartridge 210 within the molecular diagnostic module 130, the heating and cooling subsystem 150 of the molecular diagnostic module 130 is configured to transfer heat to the heating region 224 of the microfluidic cartridge 210, and the magnet 160 of the molecular diagnostic module 130 is configured to be received by the magnet housing region 218 of the microfluidic cartridge 210 to provide a magnetic field for separation of nucleic acids.”) • U.S. Patent No. 9,050,594 at 29:5-13 (“Step S430 may further comprise occluding at least one fluidic pathway of the set of fluidic pathways at a subset of a set of occlusion positions S432, which functions to define at least one truncated fluidic pathway. Preferably, Step S432 comprises defining at least one truncated fluidic pathway passing through at least one of a heating region and a magnetic field; however, Step S432 may alternatively not comprise defining a truncated fluidic pathway passing through at least one of a heating region and a
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		magnetic field.”)
1(k)	the heater assembly comprising one or more heaters aligned along a third axis parallel to the first axis when the housing is received in the bay,	<p>In the accused system, the first module further comprises a heating assembly positioned adjacent to a second side of the plurality of process chambers opposite the first side when the housing is received in the bay, the heater assembly comprising one or more heaters aligned along a third axis parallel to the first axis when the housing is received in the bay.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” <i>Id.</i> at 2:28-2:39. • <i>Id.</i> at 2:28 (showing lysate in the s-channel).  <ul style="list-style-type: none"> • “A precise volume of air is then applied to remove any remaining liquid into the waste chamber. NeuMoDx wash solution is pumped via the fluid port into the

		<p>microfluidic cartridge to remove all unbound material, followed by another volume of air to remove excess wash solution. High pH NeuMoDx release reagent is dispensed into the s-channel to cover the beads, and heat is applied to the denaturation process, resulting in released nucleic acid or eluate.” <i>Id.</i> at 2:39-3:12.</p> <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> • Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10. • Patent No. 9,382,532 at 10:3-13 (“In the variation of the specific example, the microparticles of the moiety-bound nucleic acid volume can be retained by a magnetic field within a portion of the fluidic pathway upon occlusion of the fluidic pathway at a suitable set of occlusion positions, and the elution solution can be
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		<p>delivered through the portion of the fluidic pathway enable release of the nucleic acid sample from the microparticle. Additionally, a heating element of the system can be moved proximal to the portion of the fluidic pathway with the elution solution and the microparticles to further enhance release of the nucleic acid sample.")</p> <ul style="list-style-type: none"> • Patent No. 9,382,532 at 24:1-12 ("A first illustration of the eighteenth example, as shown in FIG. 22A, of a fluidic pathway 165 preferably comprises an initial segment 174 fluidically coupled to a fluid channel 119 coupled to a shared fluid port 118, a sample segment 175 coupled to a sample port 114 and to the initial segment 174, and an s-shaped capture segment 166, configured to pass through the heating region 195 and a magnetic field 156, coupled to the initial segment 174 and the sample segment 175. In an alternative illustration of the eighteenth example, the s-shaped capture segment 166 may comprise an initial wide arc 166 to provide a greater surface area for magnetic bead capture.") <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> • Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate. • Claim 11. The cartridge of claim 10, further comprising 1) a heating region defined as a recessed region of the first layer that is parallel to the set of voids of the corrugated surface, and 2) a vent region, such that the first fluidic pathway is configured to cross the heating region and to pass through the vent region upstream of the first detection chamber, and the second fluidic pathway is
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- configured to cross the heating region and to pass through the vent region upstream of the second detection chamber.
- U.S. Patent No. 9,403,165 at 3:27-32 (“As shown in FIGS. 1B and 1C, the top layer 110 preferably comprises a set of sample port-reagent port pairs 112, a fluid port 118, a vent region 190, a **heating region 195 crossing a capture segment 166 of a fluidic pathway 165**, and a set of detection chambers 116.”)
 - U.S. Patent No. 9,403,165 at 1A.

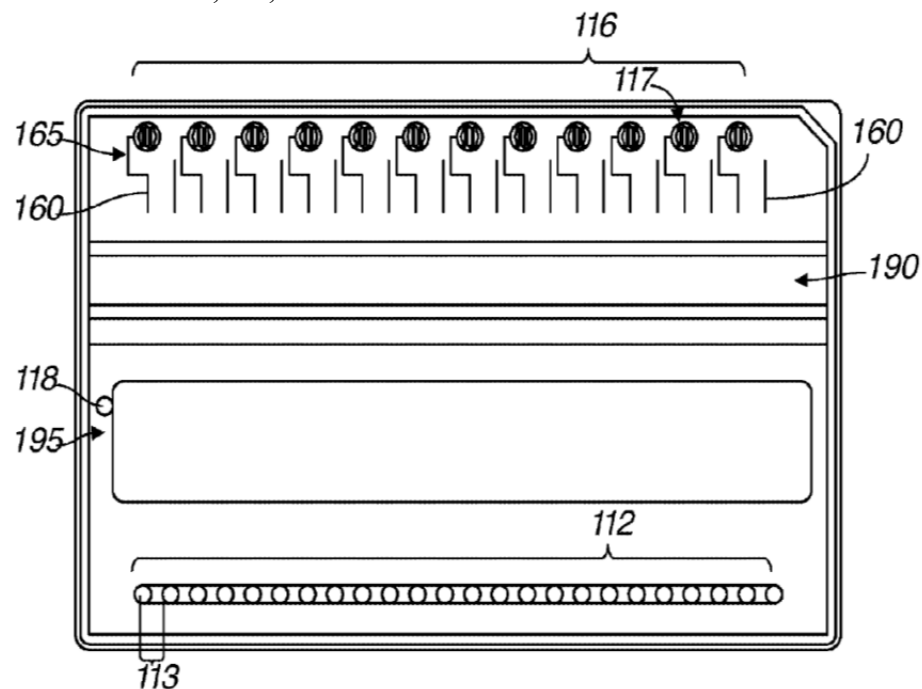


FIG. 1A

- U.S. Patent No. 9,403,165 at FIG. 1B

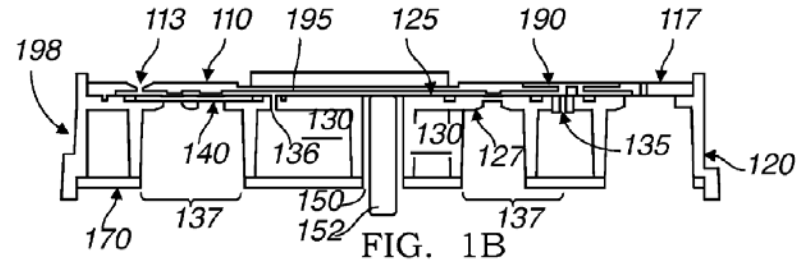


FIG. 1B

- U.S. Patent No. 9,403,165 at FIG. 1C .

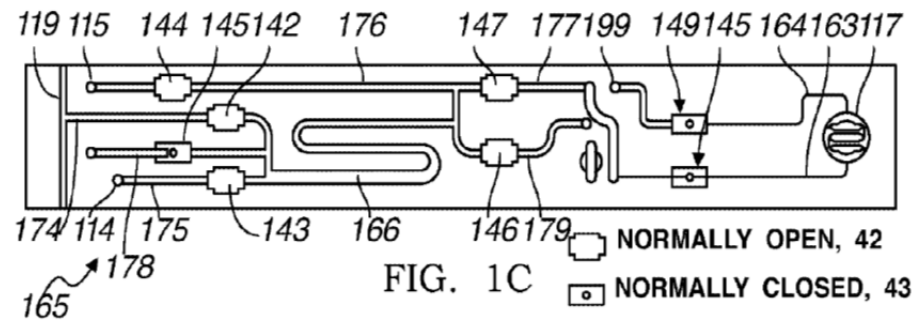
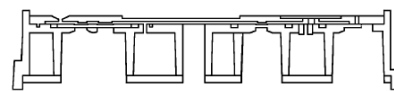


FIG. 1C

- U.S. Patent No. 9,403,165 at FIG. 9



SIDE VIEW

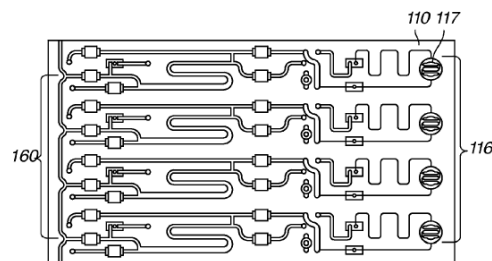


FIG. 9

TOP VIEW

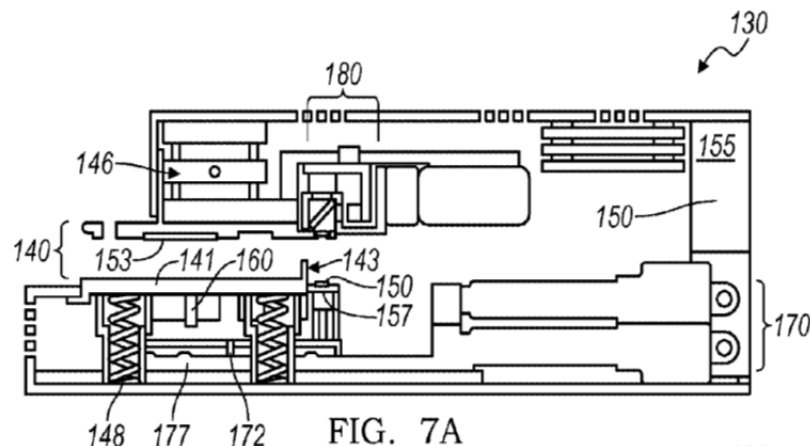
- U.S. Patent No. 9,403,165 at 14:39-50 (“As shown in FIGS. 1C, 6C, 7 and 9, a fluidic pathway 165 of the set of fluidic pathways 160 is branched and preferably comprises an initial segment 174 fluidically coupled to a fluid channel 119 coupled to a fluid port 118, a sample segment 175 coupled to a sample port 114, a reagent segment 176 coupled to a reagent port 115, **a capture segment 166 passing through at least one of the heating region 195 and a magnetic field 156**, a vent segment 177 configured to pass through the vent region 190, a segment running to a detection chamber 163, a segment running away from the detection chamber 164, and at least one waste segment 178, 179 configured to transfer a waste fluid to a waste chamber 130.”)

US9050594 (Exhibit 24)

- Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge

		<p>platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • Claim 12. The system of claim 1, wherein the molecular diagnostic module further comprises a molecular diagnostic module heater configured to heat at least one magnetic bead-sample. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module. • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier
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		<p>heater.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) • U.S. Patent No. 9,050,594 at 2:49-58 (“As shown in FIGS. 1A-1B and 7A, an embodiment of a system 100 for processing and detecting nucleic acids comprises: a capture plate 110 configured to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119; a molecular diagnostic module 130 comprising a microfluidic cartridge receiving module 140, heating and cooling subsystem 150, a magnet 160, a valve actuation subsystem 170, an optical subsystem 180; and an assay strip 190 configured to facilitate mixing of molecular diagnostic reagents with a nucleic acid volume.”) • U.S. Patent No. 9,050,594 at FIG. 7A
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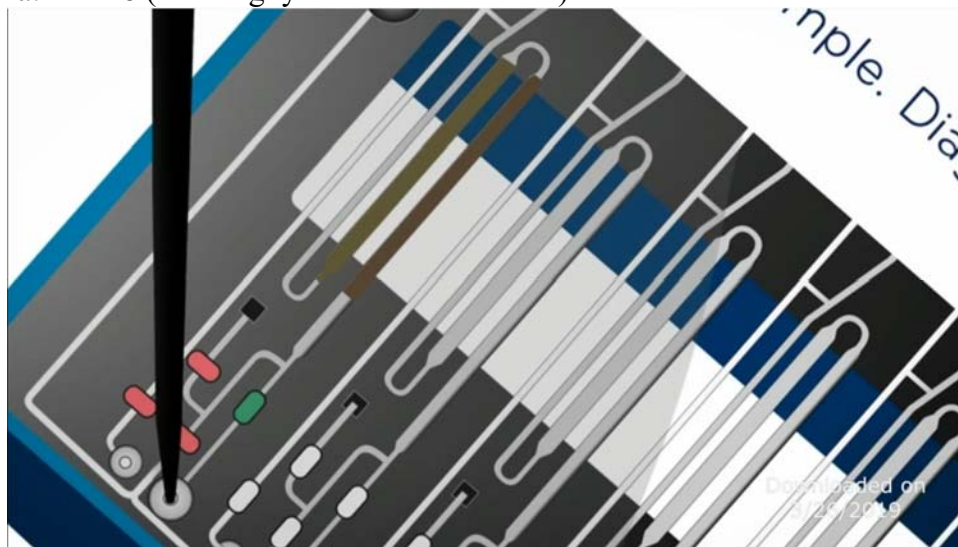


- U.S. Patent No. 9,050,594 at 10:29-48 (“The heating and cooling subsystem 150 of the molecular diagnostic module 130 comprises a cartridge heater 153, a fan 155, and a set of detection chamber heaters 157 and functions to controllably heat portions of a microfluidic cartridge 210 for processing of a biological sample containing nucleic acids according to a molecular diagnostic protocol. In the orientation of an embodiment of the molecular diagnostic module 130 shown in FIGS. 7A-7C, the cartridge heater 153 is preferably coupled to the linear actuator 146 of the cartridge receiving module 140 and configured to span a central region of a microfluidic cartridge 210 aligned within the molecular diagnostic module 130, the fan 155 is located at a back wall of the cartridge receiving module 140, and the set of detection chamber heaters 157 is located inferior to a set of detection chambers 213 of the microfluidic cartridge 210. In alternative embodiments of the molecular diagnostic module 130, the heating and cooling subsystem 150 may have any appropriate alternative configuration that provides controlled heating and cooling to a microfluidic cartridge within the molecular diagnostic module 130.”)
- U.S. Patent No. 9,050,594 at 10:49-65 (“The cartridge heater 153 functions to transfer heat to a heating region 224 of a microfluidic cartridge 210, for inducing a pH shift to release bound nucleic acids from magnetic beads within the heating region 224. The cartridge heater 153 is preferably a plate-shaped heater

		<p>configured to transfer heat to the microfluidic cartridge 210 only from one side of the cartridge heater 153, such that heat flows through one face of the plate-shaped heater to the microfluidic cartridge 210. In a specific example, the cartridge heater 153 is a silicon wafer etched to be conductive and form a resistance heater. In the preferred variation, the cartridge heater 153 is either flip-chip bonded (i.e., soldered to back side of a circuit board), or wire bonded to a circuit board, and then coupled using linear bearings and springs to a plate coupled to the linear actuator 146. The preferred variation allows independent control of 12 independent channels, corresponding to 12 different pathways for sample processing.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 13:6-12 (“In an example, as shown in FIGS. 7A-7C, the magnet 160 is a rectangular prism-shaped magnet 160 fixed under the cartridge platform 141, and configured to pass through the cartridge platform 141, into a magnet housing region 218 located under the heating region 224 of the microfluidic cartridge 210.”) • U.S. Patent No. 9,050,594 at 22:61-23:5 (“The microfluidic cartridge 210 is preferably configured to be received and manipulated by the molecular diagnostic module 130, such that the cartridge receiving module 140 of the molecular diagnostic module 130 receives and aligns the microfluidic cartridge 210 within the molecular diagnostic module 130, the heating and cooling subsystem 150 of the molecular diagnostic module 130 is configured to transfer heat to the heating region 224 of the microfluidic cartridge 210, and the magnet 160 of the molecular diagnostic module 130 is configured to be received by the magnet housing region 218 of the microfluidic cartridge 210 to provide a magnetic field for separation of nucleic acids.”)
1(l)	the heating assembly configured to heat a solution in the plurality of process chambers to between 50°C and 85°C,	<p>In the accused system, the first module further comprises a heating assembly positioned adjacent to a second side of the plurality of process chambers opposite the first side when the housing is received in the bay, the heater assembly comprising one or more heaters aligned along a third axis parallel to the first axis when the housing is received in the bay, the heating assembly configured to heat a solution in the plurality of process chambers to between 50°C and 85°C.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018,</p>

3:50 PM), <http://www.neumodx.com/our-solutions/> - linking to “VIDEO | NeuMoDx™ WORKFLOW” hyperlink at <https://player.vimeo.com/video/299307936>. (Exhibit 16)

- “Once the crude lysate is dispensed, a series of valves **directs the flow to the s-channel, where the paramagnetic beads are captured** utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” *Id.* at 2:28-2:39.
- *Id.* at 2:28 (showing lysate in the s-channel).



- “A precise volume of air is then applied to remove any remaining liquid into the waste chamber. NeuMoDx wash solution is pumped via the fluid port into the microfluidic cartridge to remove all unbound material, followed by another volume of air to remove excess wash solution. High pH NeuMoDx release reagent is dispensed into the s-channel to cover the beads, **and heat is applied to the denaturation process, resulting in released nucleic acid or eluate.**” *Id.* at 2:39-3:12.

On information and belief, in the accused system, the first module further comprises a heating assembly positioned adjacent to a second side of the plurality of process chambers opposite the first side when the housing is received in the bay, the heater assembly

		<p>comprising one or more heaters aligned along a third axis parallel to the first axis when the housing is received in the bay, the heating assembly configured to heat a solution in the plurality of process chambers to between 50°C and 85°C.</p> <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> Patent No. 9,382,532 at 9:31-62 (“In some variations, Step S160 can further comprise Step S161, which recites heating the moiety-bound nucleic acid volume. Step S161 functions to provide additional environmental conditions that facilitate release of the nucleic acid sample from the microparticles, and can further function to mitigate effects of proteolytic enzymes that are used in Steps S110, S120, and/or S130 or that may be released from the biological sample containing the nucleic acid. Preferably, an elevated temperature in combination with an elevated pH resulting from the elution solution provides the enhanced conditions to facilitate the release of the nucleic acid sample. Furthermore, an elevated temperature (e.g., elevating a sample eluted at room temperature to 85 C) can function to minimize protease enzyme activity in the eluted nucleic acid and thereby improve the robustness of the detection of the target nucleic acid sample during processing in variations of Step S110; however, the method 100 can alternatively omit Step S161 in applications wherein heating the moiety-bound nucleic acid volume is undesirable and/or unnecessary. Furthermore, variations of Step S161 can comprise heating at higher temperatures for shorter time periods, or heating at lower temperatures for longer time periods. In an example of Step S161, heating comprises elevating the temperature of the moiety-bound nucleic acid volume to 80-85 C, for 3 minutes, and in another example, heating comprises elevating the temperature of the moiety-bound nucleic acid volume to 50-70 C, for 3-10 minutes. In other examples, the elevation temperature can be maintained at a desired set-point for as low as 1 minute or as high as 30 minutes. Further, elution conditions may be optimized to ensure that the bound nucleic acid is only eluted in the presence of the high pH solution at the elevated temperature for a specified amount of time.”) Patent No. 9,382,532 at 10:46-57 (“In specific examples, however, Step S165 can comprise any combination of: not washing the moiety-bound nucleic acid volume,
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		<p>passively washing the moiety-bound nucleic acid volume, not removing a wash solution from the moiety-bound nucleic acid volume, washing the moiety-bound nucleic acid volume with a Tris solution (e.g., 1 mM Tris solution), eluting the nucleic acid sample at room temperature, eluting the nucleic acid sample at 99 C, eluting the nucleic acid sample at 55 C, and not resuspending moiety-bound microparticles in a release buffer, any combination of which can affect amplification of the nucleic acids or the process control.”)</p> <ul style="list-style-type: none"> • Patent No. 9,382,532 at 13:42-60 (“A first example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, cerebrospinal fluid (CSF) as a representative biological sample, and Enterovirus (EV) viral particles as the model target. In the first example, 200 μL of CSF was spiked with 2 μL of EV viral particle lysate and then mixed with 500 μL of RNA Collection Buffer 1 (CBR-1) and 300 μL of nuclease-free water in examples of Steps S110 and S120. As a comparison, a similar amount of EV particle lysate was spiked into a 1 mL solution comprised of 500 μL of CBR-1 buffer and 500 μL of nuclease-free water and processed simultaneously. In an example of Step S130, RNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 60 C. Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2\times) with 500 μL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) <i>See also id.</i> at 14:5-23, 14:41-59, 15:8-24, 15:36-55, 15:58-6:12, 16:29-44, 16:61-17:10, 17:27-43, 17:60-18:14, 18:31-47, 19:12-27, 19:46-61, 20:7-23, 20:33-50, 21:23-39, 21:59-22:8, 22:31-49. • Patent No. 9,382,532 at 15:36-55 (“In other variations of the first through fourth examples involving RNA extractions, the example method 100 can comprise any suitable combination of: adding guanidine to an RNA lysis buffer (e.g., 50 mM GuSCN), adding guanidine to a swab extraction buffer (e.g., 2M GuHCL, 2.5M GuHCL), providing any suitable lysis buffer (e.g., 50 mM TRIS pH 7 with 1 % Triton X, 50 mM EDTA, and 2M GuHCL; 1 mM Tris pH 8 in 1% Triton X and 100 mM EDTA), binding RNA to affinity moiety-coated microparticles at any suitable temperature (e.g., 37-60 C for up to 10 minutes), using any suitable amount (e.g., 7 .5 ug) of tRNA during lysis, using fresh or frozen samples, providing any
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		suitable wash conditions (e.g, 1x salt wash, 1x salt wash+1x 1 mM TRIS pH 8 wash), providing any suitable binding conditions (e.g., 2x 1 mM TRIS pH 8 binding at 37 C, 2x 1 mM TRIS pH 8 at 60 C), eluting with any suitable elution conditions (e.g., room temperature to 85 C, 1 minute-10 minutes) , providing any suitable composition of an elution solution (e.g., 20 mM Na OH, 40 mM Na OH, KOH), and using any suitable PCRMix for EV extractions.”)
1(m)	the one or more complementary registration members configured to align the plurality of process chambers with the heater assembly when the housing is received in the bay; and	<p>In the accused system, the first module further comprises a heating assembly positioned adjacent to a second side of the plurality of process chambers opposite the first side when the housing is received in the bay, the heater assembly comprising one or more heaters aligned along a third axis parallel to the first axis when the housing is received in the bay, the heating assembly configured to heat a solution in the plurality of process chambers to between 50°C and 85°C, the one or more complementary registration members configured to align the plurality of process chambers with the heater assembly when the housing is received in the bay.</p> <p><i>NeuMoDx Molecular N288 System</i>, http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ TECHNOLOGY” hyperlink at https://player.vimeo.com/video/281470603. (Exhibit 17)</p> <ul style="list-style-type: none"> • At 4:17 (showing a plurality of multi-lane microfluidic cartridges in a plurality of receiving bays)



- at 4:55-5:00 (showing a plurality of multi-lane microfluidic cartridges in a plurality of receiving bays)





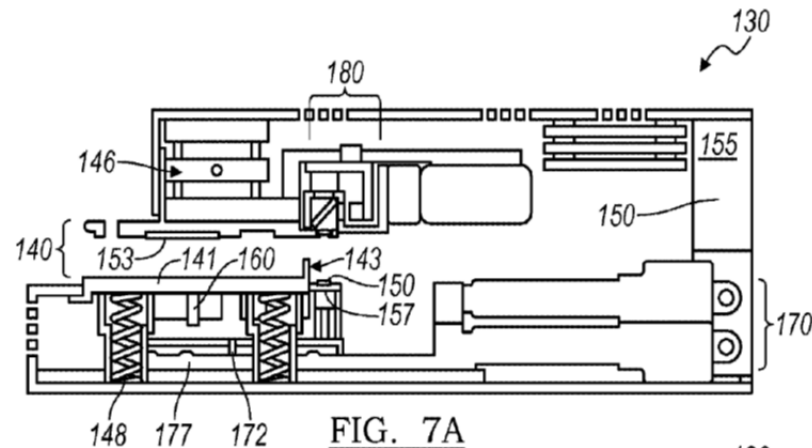
US9050594 (Exhibit 24)

- Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.
- Claim 12. The system of claim 1, wherein the molecular diagnostic module further comprises **a molecular diagnostic module heater configured to heat at least one magnetic bead-sample.**
- Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to

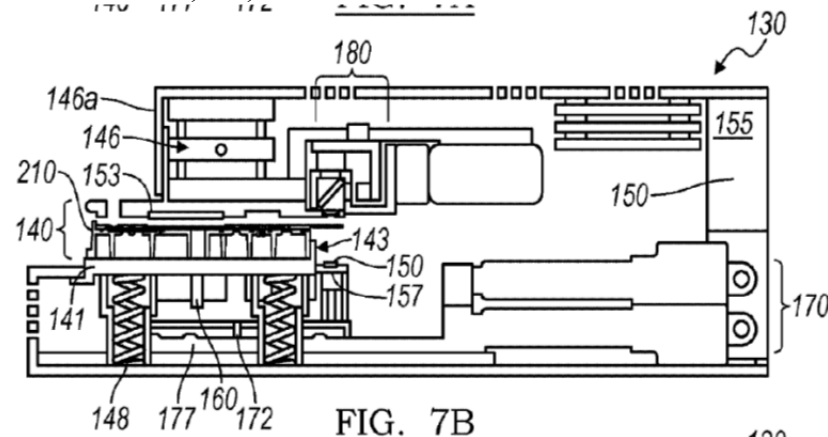
		<p>produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at 8:60-9:15 (“The linear actuator 146 functions to linearly displace a microfluidic cartridge 210 resting on the cartridge platform 141, in order to compress the microfluidic cartridge 210 and position the microfluidic cartridge 210 between a cartridge heater 153 and an optical subsystem 180 on one side of the microfluidic cartridge 210, and a magnet 160 and detection chamber heaters 157 on another side of the microfluidic cartridge 210. The linear actuator 146 also functions to provide a sufficient counterforce to the valve actuation subsystem 170 such that a microfluidic cartridge 210 within the molecular diagnostic module 130 remains properly situation upon manipulation by the valve actuation subsystem 170. The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210. In the orientation of the molecular diagnostic module 130 shown in FIGS. 7B and 7B [sic], the linear actuator 146 is preferably coupled to a portion of the heating and cooling subsystem 150 a portion of the optical subsystem 180, and the nozzle 149,
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and vertically displaces the cartridge heater 153, the optical subsystem 180, and the nozzle 149 to position the cartridge heater 153, 180 and the nozzle 149 over the microfluidic cartridge 210.”)

- U.S. Patent No. 9,050,594 at FIG. 7A



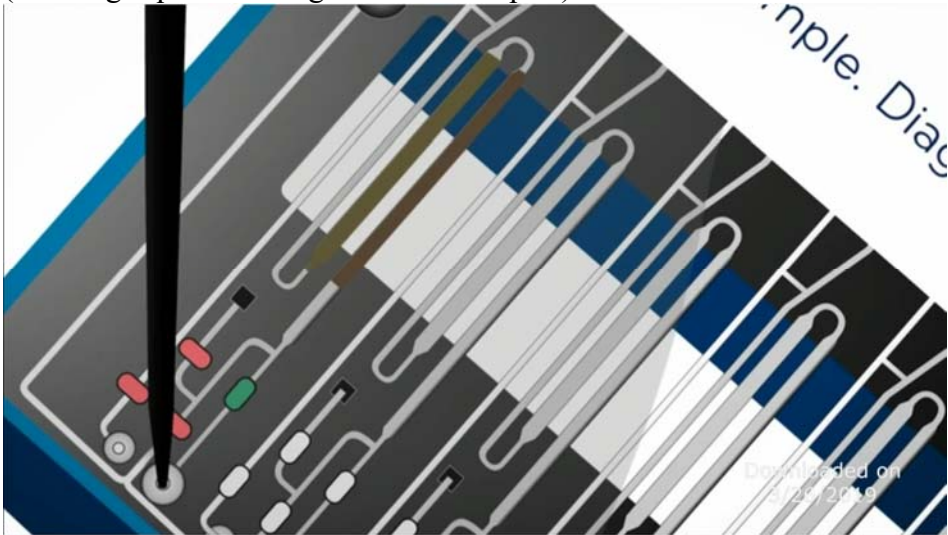
- U.S. Patent No. 9,050,594 at FIG. 7B

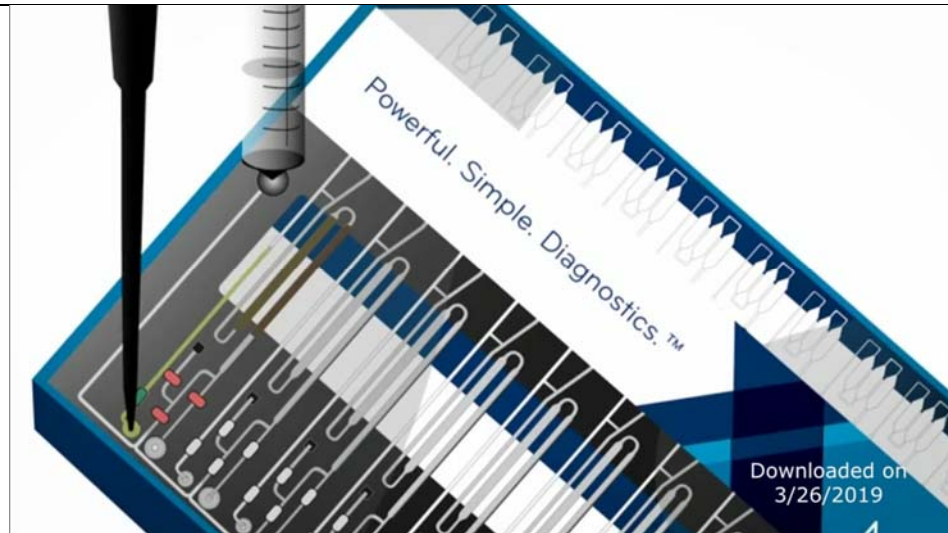


- U.S. Patent No. 9,050,594 at 10:5-26 (“Similarly, the nozzle 149, the heating and cooling subsystem 150, the cartridge heater 153, and the magnet 160 are preferably coupled to springs, such that springs are positioned between

		<p>elements 149,150, 153, and 160, and substrates that elements 149, 150, 153, and 160 are mounted to. Alternatively an elastomeric material is preferably positioned between elements 149,150, 153, and 160, and substrates that elements 149, 150, 153, and 160 are mounted to. The springs and/or elastomeric material function to provide proper functioning and alignment of subsystems of the molecular diagnostic module 130 as the linear actuator 146 is extended or retracted, contributing to reliability and a reduction in stack up tolerance risk. The springs and/or elastomeric material further function to allow more pressure to be applied to occlusion positions of a microfluidic cartridge 210 aligned within the molecular diagnostic module 130, and an appropriate pressure to be applied to elements 149, 150, 153 and 160 of the molecular diagnostic module 130. Thus, proper contact is maintained between elements 149, 150, 153, and 160, and a microfluidic cartridge 210 being manipulated by the molecular diagnostic module. These elements are described in further detail below.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 10:29-48 (“The heating and cooling subsystem 150 of the molecular diagnostic module 130 comprises a cartridge heater 153, a fan 155, and a set of detection chamber heaters 157 and functions to controllably heat portions of a microfluidic cartridge 210 for processing of a biological sample containing nucleic acids according to a molecular diagnostic protocol. In the orientation of an embodiment of the molecular diagnostic module 130 shown in FIGS. 7A-7C, the cartridge heater 153 is preferably coupled to the linear actuator 146 of the cartridge receiving module 140 and configured to span a central region of a microfluidic cartridge 210 aligned within the molecular diagnostic module 130, the fan 155 is located at a back wall of the cartridge receiving module 140, and the set of detection chamber heaters 157 is located inferior to a set of detection chambers 213 of the microfluidic cartridge 210. In alternative embodiments of the molecular diagnostic module 130, the heating and cooling subsystem 150 may have any appropriate alternative configuration that provides controlled heating and cooling to a microfluidic cartridge within the molecular diagnostic module 130.”) • U.S. Patent No. 9,050,594 at 11:13-32 (“Preferably, the cartridge heater 153 is configured to linearly translate with the linear actuator 146 of the cartridge receiving module 140, in order to align with a heating region 224 spanning a
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		<p>central portion of a microfluidic cartridge 210 aligned within the molecular diagnostic module 130. In one variation, the cartridge heater 153 is preferably fixed relative to the linear actuator 146 such that (in the orientation shown in FIGS. 7B-7C), the cartridge heater 153 can only move vertically with the linear actuator. In an alternative variation, the cartridge heater 153 may additionally be configured to translate laterally with a horizontal plane (in the orientation shown in FIGS. 7B-7C), such that the cartridge heater 153 can translate in at least two perpendicular coordinate planes. In this alternative variation, the cartridge heater 153 can be configured to sweep across a surface of a microfluidic cartridge 210 aligned within the molecular diagnostic module 130, or to translate in response to motion of the microfluidic cartridge 210, such that the position of the cartridge heater 153 relative to a heating region 224 of the microfluidic cartridge 210 is always fixed.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 22:61-23:5 (“The microfluidic cartridge 210 is preferably configured to be received and manipulated by the molecular diagnostic module 130, such that the cartridge receiving module 140 of the molecular diagnostic module 130 receives and aligns the microfluidic cartridge 210 within the molecular diagnostic module 130, the heating and cooling subsystem 150 of the molecular diagnostic module 130 is configured to transfer heat to the heating region 224 of the microfluidic cartridge 210, and the magnet 160 of the molecular diagnostic module 130 is configured to be received by the magnet housing region 218 of the microfluidic cartridge 210 to provide a magnetic field for separation of nucleic acids.”)
1(n)	a liquid dispenser configured to move between a first location and a second location when the housing is received in the bay,	<p>The accused system comprises a liquid dispenser configured to move between a first location and a second location when the housing is received in the bay.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “Liquid Handling Processing B: Extraction. After thoroughly mixing the solution in each well of the extraction plate, the crude lysate is independently aspirated from each well and transferred to the NeuMoDx cartridge.” <i>Id.</i> at 1:35-1:51. • “The liquid handling robot employs total aspiration and dispense monitoring

		<p>pressure sensing to ensure each tip is securely seated into one of the 12 independent sample ports or s-ports of the cartridge. Once the pipette tip is secured, the entire volume of solution will be dispensed.” <i>Id.</i> 2:02-2:24. <i>Id.</i> at 2:28 (showing liquid handling robot at the s-port)</p>  <ul style="list-style-type: none"> • “The liquid handling robot aspirates the PCR-ready solution and transfers it back to the cartridge where it dispenses into the same p-port from which the sample was aspirated. A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:57-4:08. • <i>Id.</i> at 3:57 (showing the liquid handling robot at the p-port).
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NeuMoDx Molecular N288 System, <http://www.neumodx.com/our-solutions/> - linking to "VIDEO | NeuMoDx™ TECHNOLOGY" hyperlink at <https://player.vimeo.com/video/281470603>. (Exhibit 17)

- At 4:17 (showing the liquid dispenser at the microfluidic cartridge)

		 <ul style="list-style-type: none">• At 4:29 (showing the liquid dispenser at the reagent strip)
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- At 4:36 (showing the liquid dispenser returning to the microfluidic cartridge)



		<p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> • Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position of the fluidic pathway, by way of the void of the corrugated surface, the fluidic pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber. • Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate. • Claim 10. The cartridge of claim 8, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second
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		<p>sample port-reagent port pair and the second detection chamber, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,403,165 at 3:33-3:43 (“Each sample-port-reagent port pair 113 of an embodiment of the top layer 110 comprises a sample port 114 and a reagent port 115. The sample port 114 functions to receive a volume of a sample fluid potentially containing the nucleic acids of interest for delivery of the volume of fluid to a portion of a fluidic pathway 165 coupled to the sample port-reagent port pair 113. In a specific embodiment, the volume of a sample fluid is a biological sample with magnetic beads for nucleic acid isolation; however, the volume of fluid comprising a sample fluid may alternatively be any appropriate fluid containing a sample with nucleic acids.”) • U.S. Patent No. 9,403,165 at 3:53-66 (“Each sample-port reagent port pair 113 of an embodiment of the top layer 110 also comprises a reagent port 115, as shown in FIG. 1A. The reagent port 115 in a sample port-reagent port pair 113 functions to receive a volume of fluid comprising a reagent used in molecular diagnostics, for delivery of the volume of fluid comprising a reagent to a portion of a fluidic pathway 165 coupled to the sample port-reagent port pair 113. In a specific embodiment, the volume of fluid comprising a reagent used in molecular diagnostics is a sample of reconstituted molecular diagnostic reagents mixed with nucleic acids released and isolated using the microfluidic cartridge 100; however, the volume of fluid comprising a reagent used in molecular diagnostics may alternatively be any appropriate fluid comprising reagents used in molecular diagnostics. Preferably, each reagent port 115 is isolated from all other reagent ports, in order to prevent cross-contamination between samples of nucleic acids being analyzed. Additionally, each reagent port 115 is preferably of an appropriate geometric size to accommodate a standard-size pipette tip used to deliver the volume of fluid comprising a reagent used in molecular diagnostics.”) • U.S. Patent No. 9,403,165 at 4:43-55 (“Preferably, the fluid port 118 is located along an edge of the microfluidic cartridge 100, which functions to increase accessibility to the fluid port by a system delivering fluids to the fluid port 118. In a specific embodiment, as shown in FIG. 1A, the fluid port is located approximately midway along an edge of the microfluidic cartridge 100, different
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		<p>from the edge along which the set of sample port-reagent port pairs 112 is located. Alternatively, the fluid port 118 may not be located along an edge of the microfluidic cartridge 100. Additionally, the fluid port 118 is preferably configured to be coupled to a syringe pump for fluid delivery; however, the fluid port 118 may alternatively configured to couple to any appropriate system for fluid delivery.")</p> <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 2. The system of claim 1, further comprising a liquid handling system configured to transfer at least one magnetic bead-sample from the capture plate to the molecular diagnostic module, and to aspirate at least one nucleic acid volume from the molecular diagnostic module. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent
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		<p>mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 23. A system for processing and detecting nucleic acids, comprising: a molecular diagnostic module, configured to process a set of biological samples combined with magnetic beads and separate a set of nucleic acid volumes from the set of biological samples combined with magnetic beads, wherein the molecular diagnostic module comprises an actuator configured to displace a cartridge, a set of pins, and at least one cam contacting the set of pins, wherein an extension or retraction of the actuator moves the cartridge, and a displacement of a subset of the set of pins defines a set of pathways in the cartridge, each configured to receive a biological sample combined with magnetic beads of the set of biological samples combined with magnetic beads. • Claim 24. The system of claim 23, further comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample, a lysing reagent, and a sample process control, wherein the capture plate facilitates production of at least one biological sample combined with magnetic beads; an assay strip comprising at least one reagent well containing a molecular diagnostic reagent volume configured to be combined with a nucleic acid volume of the set of nucleic acid volumes to produce at least one nucleic acid-reagent mixture; and a liquid handling system configured to transfer at least one biological sample combined with magnetic beads from the capture plate to the molecular diagnostic module, transfer at least one nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer at least one nucleic acid-reagent mixture from the assay strip back to the molecular diagnostic module. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and
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		<p>detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 2:49-3:1 (“As shown in FIGS. 1A-1B and 7A, an embodiment of a system 100 for processing and detecting nucleic acids comprises: a capture plate 110 configured to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119; a molecular diagnostic module 130 comprising a microfluidic cartridge receiving module 140, heating and cooling subsystem 150, a magnet 160, a valve actuation subsystem 170, an optical subsystem 180; and an assay strip 190 configured to facilitate mixing of molecular diagnostic reagents with a nucleic acid volume. Other embodiments of the system 100 may further comprise at least one of a capture plate module 120 configured to support the capture plate 110; a filter 200 and filter holder 205 to facilitate sample preparation; a microfluidic cartridge 210 configured to facilitate sample processing; an assay strip holder 230; an assay strip carrier 240; a liquid handling system 250 configured to facilitate gas and fluid delivery to different elements of the system 100; a processor configured to analyze data resulting from a run of the system 100; and a user interface configured to allow a user to interact with the system 100.”) • U.S. Patent No. 9,050,594 at FIG. 1A.
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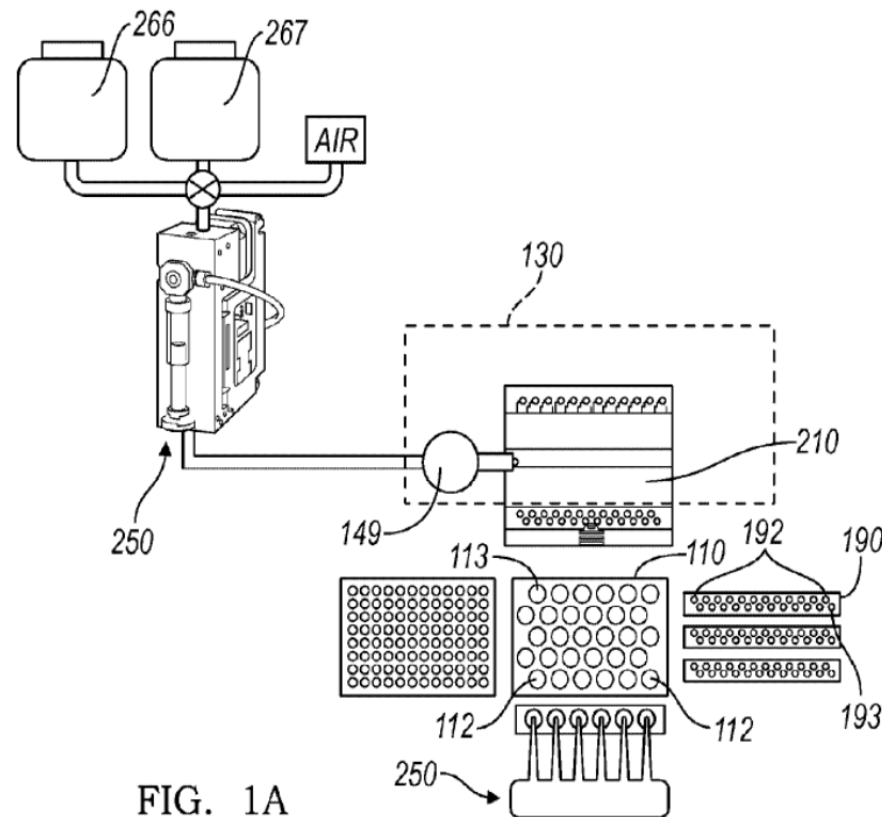
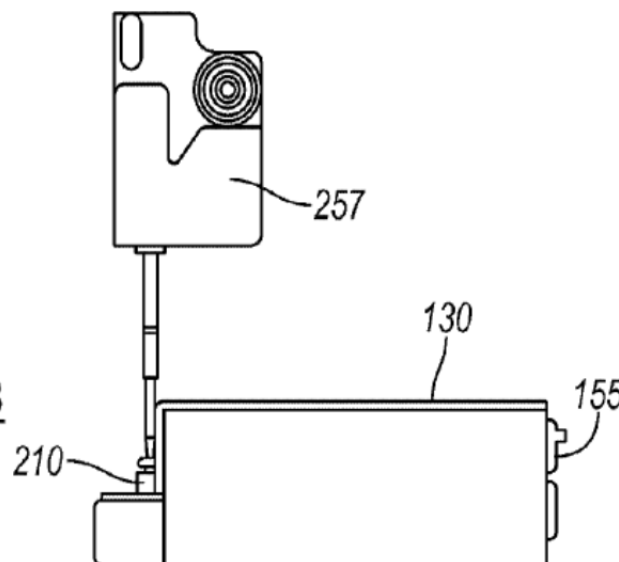


FIG. 1A

- U.S. Patent No. 9,050,594 at 3:20-41 (“The liquid handling system 250 then aspirates substantially all of each sample of the set of lysed biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate no [sic], and dispenses the set of magnetic bead-samples into a microfluidic cartridge 210, aligned within a cartridge receiving module 140 of a molecular diagnostic module 130, and configured to be manipulated by the molecular diagnostic module 130. A heating and cooling subsystem 150, a magnet 160, and a valve actuation subsystem 170 of the molecular diagnostic module 130 then facilitate separation of a set of nucleic acids from the magnetic bead-samples, as the liquid handling system 250 dispenses wash solutions, release solutions,

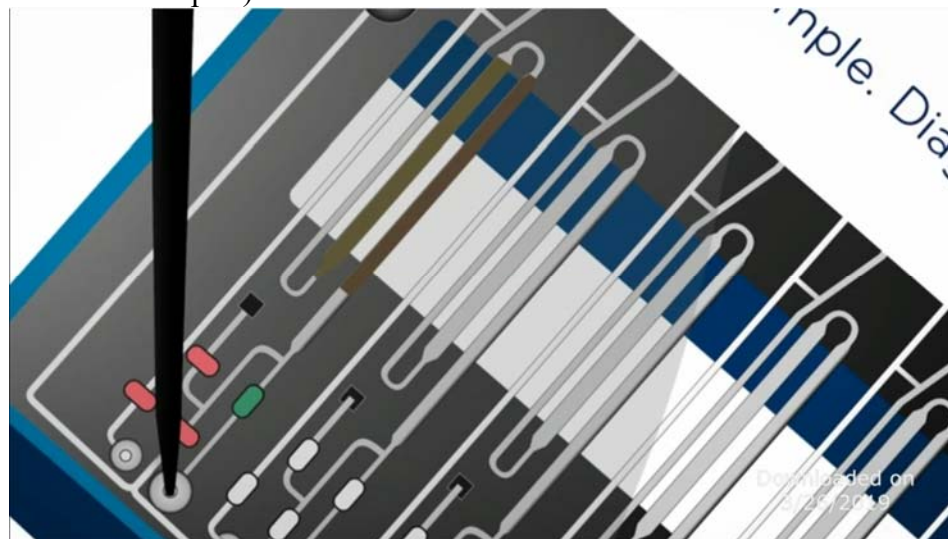
		<p>and/or air at appropriate stages. The liquid handling system 250 then aspirates the set of nucleic acids from the microfluidic cartridge 210 contained within the molecular diagnostic module 130, combines the set of nucleic acids with a set of molecular diagnostic reagents using an assay strip 190, and dispenses the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the microfluidic cartridge 210 within the molecular diagnostic module 130.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 23:28-53 (“The liquid handling system 250 of the system 100 includes a liquid handling arm 255 and a syringe pump 265, as shown in FIGS. 14A-14C and functions to deliver biological samples, reagents, and gases to elements of the system 100. As described in Section 1, an embodiment of the liquid handling system 250 is configured to aspirate a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), dispense the set of biological samples into a capture plate no [sic] to be lysed and combined with magnetic beads by a capture plate module 120, aspirate the set of biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate 110, and dispense the set of magnetic bead-samples into microfluidic cartridge 210 located in a molecular diagnostic module 130. The embodiment of the liquid handling system 100 is further configured to facilitate separation of a set of nucleic acids from the magnetic bead-samples, by dispensing a wash solution, a release solution, and/or air into the molecular diagnostic module 130, by the nozzle 149 coupled to the linear actuator 146, at appropriate stages, aspirate the set of nucleic acids from the molecular diagnostic module 130, combine the set of nucleic acids with a set of molecular diagnostic reagents using an assay strip 190, and dispense the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the molecular diagnostic module 130 for further processing and analysis.”) • U.S. Patent No. 9,050,594 at FIG. 14B.
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FIG. 14B

- U.S. Patent No. 9,050,594 at 24:16-22 (“**The multichannel liquid handling head 257 functions to aspirate fluids from and deliver fluids to different elements of the system 100.** Preferably, the multichannel liquid handling head 257 is a multichannel pipette head; however, the multichannel liquid handling head 257 may alternatively be any appropriate multichannel liquid handling head configured to deliver fluids and/or gases.”)
- U.S. Patent No. 9,050,594 at 28:53-64 (“Step S430 recites **transferring each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways, and functions to isolate each of the set of nucleic acid-magnetic bead samples within separate pathways for further processing.** Preferably, all nucleic acid-magnetic bead samples in the set of nucleic acid-magnetic bead samples are transferred simultaneously to the set of fluidic pathways, but alternatively, each nucleic acid-magnetic bead sample in the set of magnetic bead-samples may be transferred to a corresponding fluidic pathway independently of the other nucleic acid-magnetic bead samples.”)


		<ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 31:32-37 (“Step S460 recites transferring each of the set of nucleic acid-reagent mixtures, through the corresponding fluidic pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers, which functions to deliver the set of nucleic acid-reagent mixtures to an isolated detection chamber for further processing and analysis.”)
1(o)	the liquid dispenser configured to dispense at least a portion of the plurality of nucleic acid-containing samples and a plurality of magnetic binding particles when the housing is received in the bay and the liquid dispenser is in the first location,	<p>The accused system comprises a liquid dispenser configured to move between a first location and a second location when the housing is received in the bay, the liquid dispenser configured to dispense at least a portion of the plurality of nucleic acid-containing samples and a plurality of magnetic binding particles when the housing is received in the bay and the liquid dispenser is in the first location.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “The liquid handling robot delivers lysis buffer and patient specimen to the extraction plate, which has 24 independent wells which contain NeuDry affinity-coated paramagnetic beads. Each mixture is aspirated and dispensed five times to ensure homogeneity of the solution. Each extraction plate well is then heated independently for 10 minutes to ensure proper lysing and binding of the nucleic acids to the paramagnetic beads.” <i>Id.</i> 0:28-1:16. “Liquid Handling Processing B: Extraction. After thoroughly mixing the solution in each well of the extraction plate, the crude lysate is independently aspirated from each well and transferred to the NeuMoDx cartridge.” <i>Id.</i> 1:35-1:51. “The liquid handling robot employs total aspiration and dispense monitoring pressure sensing to ensure each tip is securely seated into one of the 12 independent sample ports or s-ports of the cartridge. Once the pipette tip is secured, the entire volume of solution will be dispensed. Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber” <i>Id.</i> at 2:02-2:39.

- *Id.* at 1:28 (showing dispensing of the mixture of nucleic acids and paramagnetic beads at the s-port).



NeuMoDx Molecular N288 System, <http://www.neumodx.com/our-solutions/> - linking to “VIDEO | NeuMoDx™ TECHNOLOGY” hyperlink at <https://player.vimeo.com/video/281470603>. (Exhibit 17)

- At 4:17 (showing the liquid dispenser at the microfluidic cartridge)

		 <ul style="list-style-type: none">• At 4:29 (showing the liquid dispenser at the reagent strip)
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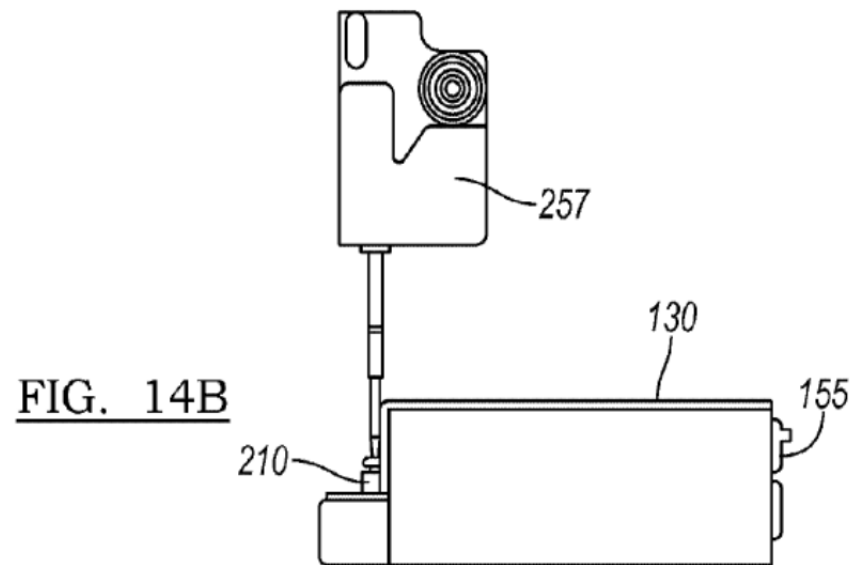
- At 4:36 (showing the liquid dispenser returning to the microfluidic cartridge)



		<p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 2. The system of claim 1, further comprising a liquid handling system configured to transfer at least one magnetic bead-sample from the capture plate to the molecular diagnostic module, and to aspirate at least one nucleic acid volume from the molecular diagnostic module. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling
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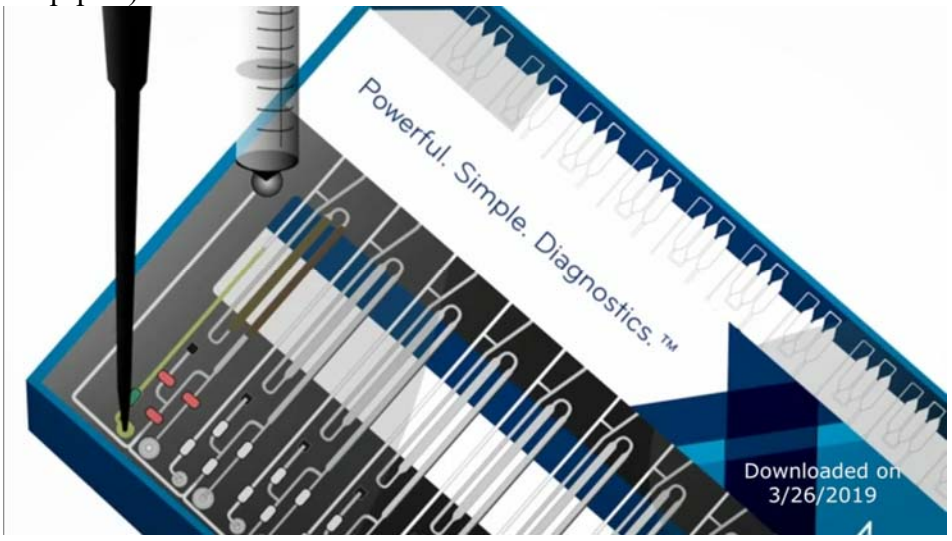
		<p>system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 23. A system for processing and detecting nucleic acids, comprising: a molecular diagnostic module, configured to process a set of biological samples combined with magnetic beads and separate a set of nucleic acid volumes from the set of biological samples combined with magnetic beads, wherein the molecular diagnostic module comprises an actuator configured to displace a cartridge, a set of pins, and at least one cam contacting the set of pins, wherein an extension or retraction of the actuator moves the cartridge, and a displacement of a subset of the set of pins defines a set of pathways in the cartridge, each configured to receive a biological sample combined with magnetic beads of the set of biological samples combined with magnetic beads. • Claim 24. The system of claim 23, further comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample, a lysing reagent, and a sample process control, wherein the capture plate facilitates production of at least one biological sample combined with magnetic beads; an assay strip comprising at least one reagent well containing a molecular diagnostic reagent volume configured to be combined with a nucleic acid volume of the set of nucleic acid volumes to produce at least one nucleic acid-reagent mixture; and a liquid handling system configured to transfer at least one biological sample combined with magnetic beads from the capture plate to the molecular diagnostic module, transfer at least one nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer at least one nucleic acid-reagent mixture from the assay strip back to the molecular diagnostic module. • U.S. Patent No. 9,050,594 at 3:20-28 (“The liquid handling system 250 then aspirates substantially all of each sample of the set of lysed biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate no [sic], and dispenses the set of magnetic bead-samples into a microfluidic cartridge 210, aligned within a cartridge receiving module 140 of a molecular diagnostic module 130, and configured to be manipulated by the molecular diagnostic module 130.”)
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- U.S. Patent No. 9,050,594 at 23:28-41 (“**The liquid handling system 250 of the system 100 includes a liquid handling arm 255 and a syringe pump 265, as shown in FIGS. 14A-14C and functions to deliver biological samples, reagents, and gases to elements of the system 100.** As described in Section 1, an embodiment of the liquid handling system 250 is configured to aspirate a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), dispense the set of biological samples into a capture plate no [sic] to be lysed and combined with magnetic beads by a capture plate module 120, aspirate the set of biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate 110, and **dispense the set of magnetic bead-samples into microfluidic cartridge 210 located in a molecular diagnostic module 130.**”)
- U.S. Patent No. 9,050,594 at FIG. 14B.



- U.S. Patent No. 9,050,594 at 28:53-64 (“**Step S430 recites transferring each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways, and**

		<p>functions to isolate each of the set of nucleic acid-magnetic bead samples within separate pathways for further processing. Preferably, all nucleic acid-magnetic bead samples in the set of nucleic acid-magnetic bead samples are transferred simultaneously to the set of fluidic pathways, but alternatively, each nucleic acid-magnetic bead sample in the set of magnetic bead-samples may be transferred to a corresponding fluidic pathway independently of the other nucleic acid-magnetic bead samples.”)</p>
1(p)	<p>the liquid dispenser further configured to dispense the nucleic acid extracted from the plurality of nucleic-acid containing samples when the liquid dispenser is in the second location.</p>	<p>The accused system comprises a liquid dispenser configured to move between a first location and a second location when the housing is received in the bay, the liquid dispenser configured to dispense at least a portion of the plurality of nucleic acid-containing samples and a plurality of magnetic binding particles when the housing is received in the bay and the liquid dispenser is in the first location, the liquid dispenser further configured to dispense the nucleic acid extracted from the plurality of nucleic-acid containing samples when the liquid dispenser is in the second location.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMoDx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “Liquid Handling Processing C: The Test Strip. After piercing the test strip, the liquid handling robot moves to the PCR port or p-port of the microfluidic cartridge, where it aspirates the eluate out of the cartridge into the pipette tip. Once the aspiration step is complete, the eluate is delivered to the appropriate wells in the NeuMoDx test strip, where it is dispensed and aspirated ten times to ensure homogeneous resuspension of the NeuDry PCR reagents. The sample mixes with primers and probes.” <i>Id.</i> at 3:12-3:57. • “The liquid handling robot aspirates the PCR-ready solution and transfers it back to the cartridge where it dispenses into the same p-port from which the sample was aspirated. A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins. During a series of independent heat on-heat off sequences, an optical scanner measures the level of fluorescence emitted, and converts it into the qualitative or quantitative results which are displayed as amplification curves for

		<p>analysis by the laboratorian.” <i>Id.</i> at 3:57-4:26.</p> <ul style="list-style-type: none"> • <i>Id.</i> at 3:57 (showing the liquid handling robot dispensing the PCR-ready solution at the p-port).  <p><i>NeuMoDx Molecular N288 System</i>, http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ TECHNOLOGY” hyperlink at https://player.vimeo.com/video/281470603. (Exhibit 17)</p> <ul style="list-style-type: none"> • At 4:17 (showing the liquid dispenser at the microfluidic cartridge)
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		 <ul style="list-style-type: none">• At 4:29 (showing the liquid dispenser at the reagent strip)
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- At 4:36 (showing the liquid dispenser returning to the microfluidic cartridge)



		<p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> • Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10. • Claim 16. The method of claim 1, further comprising processing the nucleic acid sample, wherein processing the nucleic acid sample comprises modulating the fluidic pathway of the cartridge upon displacement of a third subset of the set of pins, thereby defining a path to a diagnostic chamber of the cartridge, delivering the nucleic acid sample to the diagnostic chamber, and amplifying nucleic acids of the nucleic acid sample within the diagnostic chamber by polymerase chain reaction. • U.S. Patent No. 9,382,532 at 11:2-23 (“In one variation, the nucleic acid sample eluted from the microparticles can be aspirated (e.g., by a pipette tip or by a
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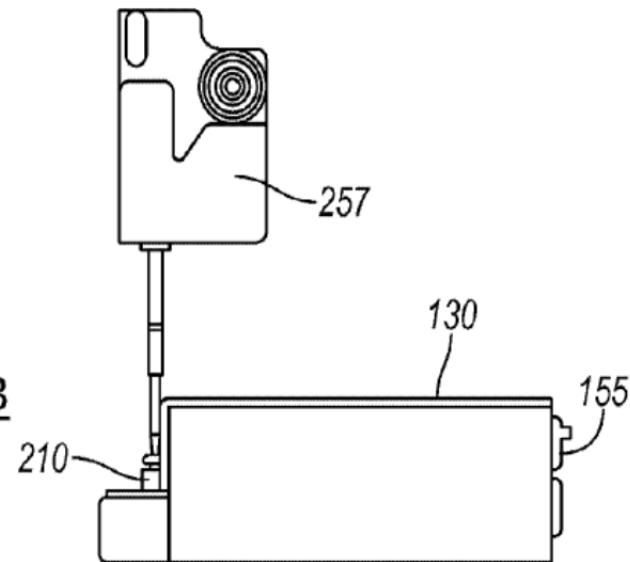
		<p>fluid handling system) into another process chamber and combined with process reagents for further processing and characterization. In a specific example of this variation, a system (such as the one described in U.S. patent application Ser. No. 13/766,359, entitled "System and Method for Processing and Detecting Nucleic Acids") can be used to aspirate the nucleic acid sample from a fluidic pathway of a cartridge (such as the one described in U.S. patent application Ser. No. 13/765,996, entitled "Microfluidic Cartridge for Processing and Detecting Nucleic Acids"), while the microparticles are immobilized by a magnet. The system can then combine the nucleic acid sample with process reagents (e.g., PCR reagents) in a separate container (e.g., assay plate), and then transfer the nucleic acid sample combined with process reagents to a detection chamber of the fluidic pathway (upon occlusion and/or opening of the fluidic channel at another subset of occlusion positions). The nucleic acid sample combined with process reagents can then be processed within a diagnostic chamber that is coupled to the fluidic pathway.")</p> <ul style="list-style-type: none"> • Patent No. 9,382,532 at 25:61-67 ("Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position (normally closed) open.") <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> • Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position of the fluidic pathway, by way of the
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		<p>void of the corrugated surface, the fluidic pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber.</p> <ul style="list-style-type: none"> • Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate. • U.S. Patent No. 9,403,165 at 17:17-23 (“Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position (normally closed) open.”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins
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		<p>contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 23. A system for processing and detecting nucleic acids, comprising: a molecular diagnostic module, configured to process a set of biological samples combined with magnetic beads and separate a set of nucleic acid volumes from the set of biological samples combined with magnetic beads, wherein the molecular diagnostic module comprises an actuator configured to displace a cartridge, a set of pins, and at least one cam contacting the set of pins, wherein an extension or retraction of the actuator moves the cartridge, and a displacement of a subset of the set of pins defines a set of pathways in the cartridge, each configured to receive a biological sample combined with magnetic beads of the set of biological samples combined with magnetic beads. • Claim 24. The system of claim 23, further comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample, a lysing reagent, and a sample process control, wherein the capture plate facilitates production of at least one biological sample combined with magnetic beads; an assay strip comprising at least one reagent well containing a molecular diagnostic reagent volume configured to be combined with a nucleic acid volume of the set of nucleic acid volumes to produce at least one nucleic acid-reagent mixture; and a liquid handling system configured to transfer at least one biological sample combined with magnetic beads from the capture plate to the molecular diagnostic module, transfer at least one nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer at least one nucleic acid-reagent mixture from the assay strip back to the molecular diagnostic module. • U.S. Patent No. 9,050,594 at 3:33-46 (“The liquid handling system 250 then aspirates the set of nucleic acids from the microfluidic cartridge 210 contained within the molecular diagnostic module 130, combines the set of nucleic acids with
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		<p>a set of molecular diagnostic reagents using an assay strip 190, and dispenses the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the microfluidic cartridge 210 within the molecular diagnostic module 130. The detection chamber heaters 157, optical subsystem 180 and valve actuation subsystem 170 of the molecular diagnostic module 130 then facilitate analysis of the set of nucleic acid-reagent mixtures by a processor configured to display information on a user interface.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 9:32-41 (“Additionally, the extended configuration 146b of the scissor jack actuator is configured to couple the nozzle 149 to a fluid port 222 of the microfluidic cartridge 210, such that the liquid handling system 250 can deliver solutions and gases for processing of biological samples. The linear actuator 146 may alternatively be any appropriate linear actuator, such as a hydraulic, pneumatic, or motor-driven linear actuator, configured to linearly displace a microfluidic cartridge within the molecular diagnostic module 130.”) • U.S. Patent No. 9,050,594 at 23:41-53 (“The embodiment of the liquid handling system 100 is further configured to facilitate separation of a set of nucleic acids from the magnetic bead-samples, by dispensing a wash solution, a release solution, and/or air into the molecular diagnostic module 130, by the nozzle 149 coupled to the linear actuator 146, at appropriate stages, aspirate the set of nucleic acids from the molecular diagnostic module 130, combine the set of nucleic acids with a set of molecular diagnostic reagents using an assay strip 190, and dispense the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the molecular diagnostic module 130 for further processing and analysis.”) • U.S. Patent No. 9,050,594 at FIG. 14B.
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FIG. 14B




- U.S. Patent No. 9,050,594 at 31:32-3 (“**Step S460 recites transferring each of the set of nucleic acid-reagent mixtures, through the corresponding fluidic pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers, which functions to deliver the set of nucleic acid-reagent mixtures to an isolated detection chamber for further processing and analysis.**”)

EXHIBIT 91

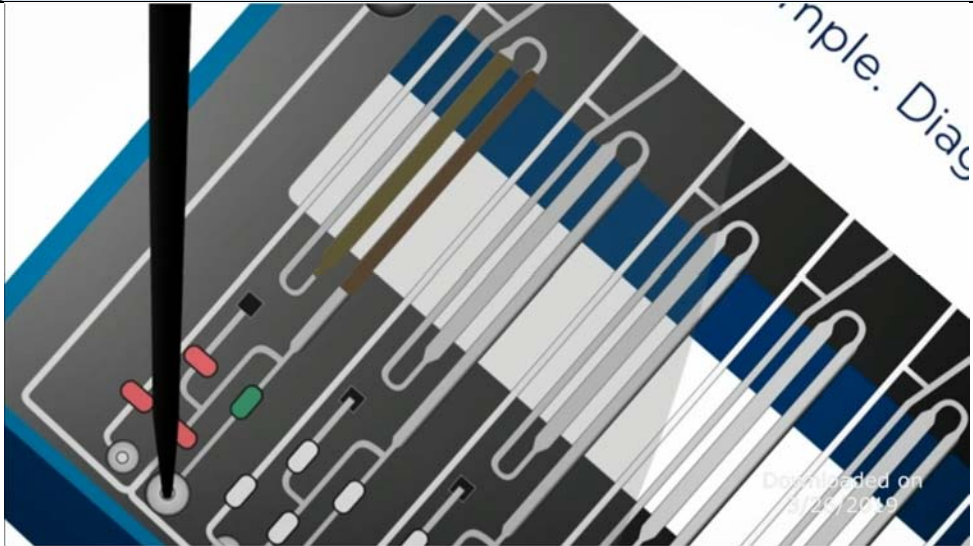
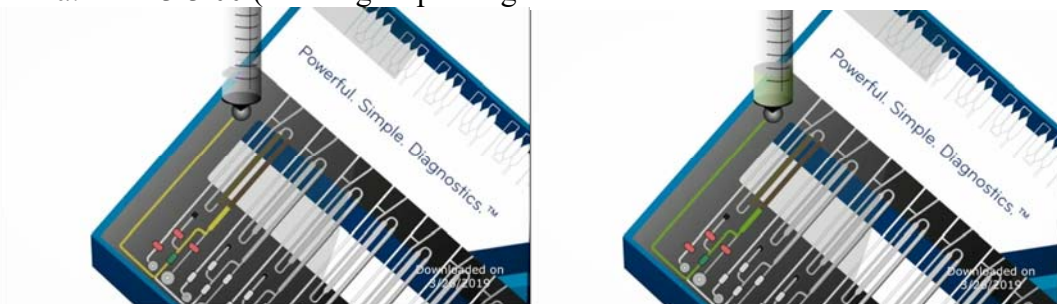
Exhibit 91


U.S. Patent Application No. 10,625,262 Infringement Chart

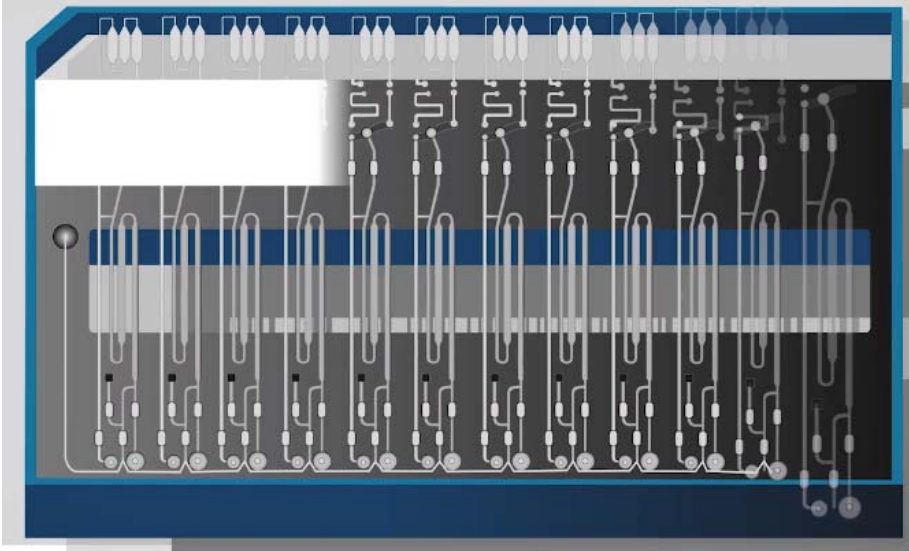
Claim	Claim Language	Infringement Evidence
1(a)	A system for processing a plurality of nucleic acid-containing samples, the system comprising:	<p>To the extent that the preamble, the accused system comprises a system for processing a plurality of nucleic acid-containing samples.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-products/, last visited June 5, 2019 (Exhibit 12)</p> 

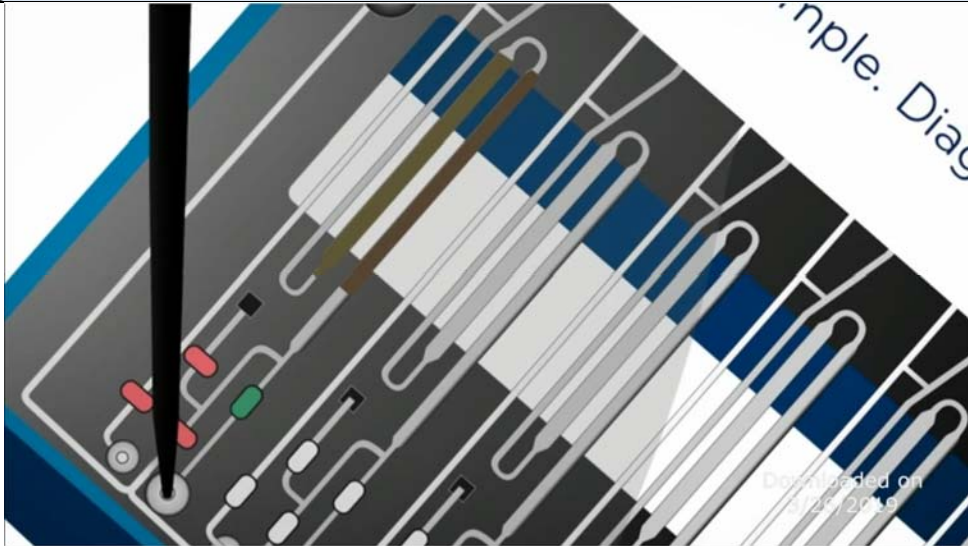
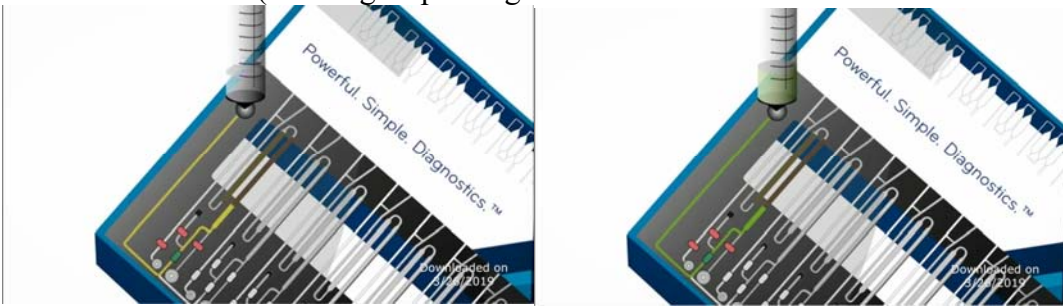
Claim	Claim Language	Infringement Evidence
		<p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul style="list-style-type: none"> • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result.” <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> • “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieveing [sic] optimal operational and clinical performance for our customers and their patients.” • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents. • “The NeuMoDx™ 96 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 288 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 288 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59

Claim	Claim Language	Infringement Evidence
		<div data-bbox="663 232 1566 776"></div> <ul style="list-style-type: none">• “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” <i>Id.</i> at 2:28-2:39.• <i>Id.</i> at 2:28 (showing lysate in the s-channel).

Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none"> • “A precise volume of air is then applied to remove any remaining liquid into the waste chamber. NeuMoDx wash solution is pumped via the fluid port into the microfluidic cartridge to remove all unbound material, followed by another volume of air to remove excess wash solution. High pH NeuMoDx release reagent is dispensed into the s-channel to cover the beads, and heat is applied to the denaturation process, resulting in released nucleic acid or eluate.” <i>Id.</i> at 2:39-3:12. • <i>Id.</i> at 2:43-3:00 (showing dispensing of the wash solution and release solution)  <p><i>NeuMoDx™</i> Molecular Systems, NEUMODX, http://www.neumodx.com/dr-steven-young-video-testimonial/, hyperlink at https://youtu.be/vukP6gbLBYE. (Exhibit 32)</p> <ul style="list-style-type: none"> • At 2:58-3:18 (“There’s two systems that have been put into operation by NeuMoDx. One is the 288.

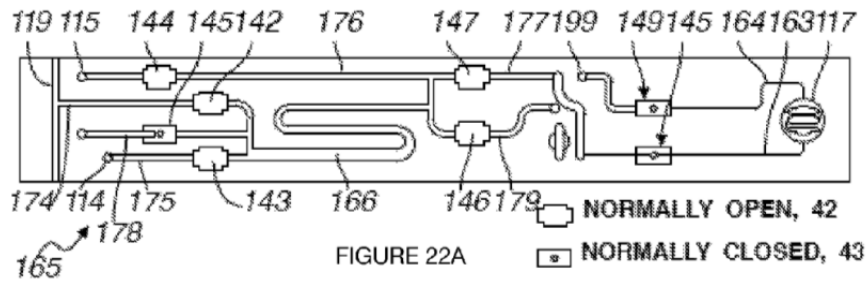
Claim	Claim Language	Infringement Evidence
		<p>It's a high-throughput instrument, versus the 96, which is a lower throughput instrument. The advantage is that both systems use all of the same chemistry and all of the same hardware. Its just a smaller footprint.”)</p>
1(b)	<p>a first module configured to extract nucleic acids from the plurality of nucleic acid-containing samples,</p>	<p>The accused system comprises a first module configured to extract nucleic acids from the plurality of nucleic acid-containing samples.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “Liquid Handling Processing A: Lysis and Capture. Dispensing lysis buffer. Dispensing lysis buffer and patient specimen into extraction plate. The liquid handling robot delivers lysis buffer and patient specimen to the extraction plate, which has 24 independent wells which contain NeuDry affinity-coated paramagnetic beads. Each mixture is aspirated and dispensed five times to ensure homogeneity of the solution. During the transfer of patient specimen to the extraction plate the liquid handling robot uses pre-defined no-fly zones to reduce the potential of contamination.” <i>Id.</i> at 0:28-1:05 • <i>Id.</i> at 0:40 (showing the extraction plate).  <p>Downloaded on 3/26/2019</p> <ul style="list-style-type: none"> • “Each extraction plate well is then heated independently for 10 minutes to ensure proper lysing and binding of the nucleic acids to the paramagnetic beads. The temperatures applied range from 37

Claim	Claim Language	Infringement Evidence
		<p>degrees Celsius to 60 degrees Celsius, resulting in the flexibility to process a wide variety of DNA and RNA IVD and LDT tests simultaneously.” <i>Id.</i> at 1:05-1:35</p> <ul style="list-style-type: none"> • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59  <ul style="list-style-type: none"> • “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” <i>Id.</i> at 2:28-2:39. • <i>Id.</i> at 2:28 (showing lysate in the s-channel).

Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none"> • “A precise volume of air is then applied to remove any remaining liquid into the waste chamber. NeuMoDx wash solution is pumped via the fluid port into the microfluidic cartridge to remove all unbound material, followed by another volume of air to remove excess wash solution. High pH NeuMoDx release reagent is dispensed into the s-channel to cover the beads, and heat is applied to the denaturation process, resulting in released nucleic acid or eluate.” <i>Id.</i> at 2:39-3:12. • <i>Id.</i> at 2:43-3:00 (showing dispensing of the wash solution and release solution) 

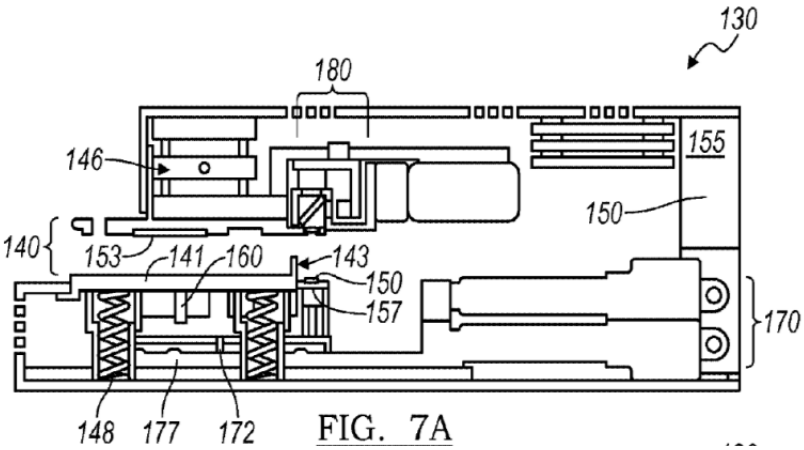
Claim	Claim Language	Infringement Evidence										
		<p>“Patents”, http://www.neumodx.com/patents/ (Exhibit 47), demonstrating that NeuMoDx marks its products with US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; 9,452,430; 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; 10,010,888; 9,382,532; 9,540,636; 9,499,896; 10,239,060; 9,539,576; 10,226,771, 9,637,775; and 10,093,963</p> <h2>PATENTS</h2> <table><tr><th>Product</th><th>Patents</th></tr><tr><td>CARTRIDGE</td><td>US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.</td></tr><tr><td>P02 (overall system and method)</td><td>US Patent Nos. 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; and 10,010,888. CN Patent No. 201380009286.3.</td></tr><tr><td>EXTRACTION PLATE</td><td>US Patent Nos. 9,382,532; and 9,540,636. DE Patent No. 60 2013 056 932.0. DK Patent No. 2912174. EP Patent No. EP-B-2912174. ES Patent No. 300330453. FR Patent No. 2912174. GB Patent No. 2912174. IT Patent No. 502019000064944. NO Patent No. 2912174. SE Patent No. 2912174.</td></tr><tr><td>XPCR MODULE</td><td>US Patent Nos. 9,499,896; 10,239,060; 9,539,576; 10,226,771; 9,637,775; 10,093,963; 9,604,213; and 10,010,888.</td></tr></table> <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none">Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a	Product	Patents	CARTRIDGE	US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.	P02 (overall system and method)	US Patent Nos. 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; and 10,010,888. CN Patent No. 201380009286.3.	EXTRACTION PLATE	US Patent Nos. 9,382,532; and 9,540,636. DE Patent No. 60 2013 056 932.0. DK Patent No. 2912174. EP Patent No. EP-B-2912174. ES Patent No. 300330453. FR Patent No. 2912174. GB Patent No. 2912174. IT Patent No. 502019000064944. NO Patent No. 2912174. SE Patent No. 2912174.	XPCR MODULE	US Patent Nos. 9,499,896; 10,239,060; 9,539,576; 10,226,771; 9,637,775; 10,093,963; 9,604,213; and 10,010,888.
Product	Patents											
CARTRIDGE	US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.											
P02 (overall system and method)	US Patent Nos. 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; and 10,010,888. CN Patent No. 201380009286.3.											
EXTRACTION PLATE	US Patent Nos. 9,382,532; and 9,540,636. DE Patent No. 60 2013 056 932.0. DK Patent No. 2912174. EP Patent No. EP-B-2912174. ES Patent No. 300330453. FR Patent No. 2912174. GB Patent No. 2912174. IT Patent No. 502019000064944. NO Patent No. 2912174. SE Patent No. 2912174.											
XPCR MODULE	US Patent Nos. 9,499,896; 10,239,060; 9,539,576; 10,226,771; 9,637,775; 10,093,963; 9,604,213; and 10,010,888.											

Claim	Claim Language	Infringement Evidence
		<p>second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at Abstract (“A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber; mixing the binding moiety solution with a biological sample, within the process chamber, in order to produce a moiety-sample mixture; incubating the moiety-sample mixture during a time window, thereby producing a solution comprising a set of moiety-bound nucleic acid particles and a waste volume; separating the set of moiety-bound nucleic acid particles from the waste volume; washing the set of moiety-bound nucleic acid particles; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles.”) • U.S. Patent No. 9,382,532 at 7:14-54 (“In Step S140, the lysed moiety-sample solution can be processed within the process chamber to separate the moiety-bound nucleic acid volume from the waste volume; however, the lysed moiety-sample solution can alternatively be transferred to another suitable vessel for separation of the moiety-bound nucleic acid volume from the waste volume. In a first variation, a pipetting system (automatic or manual) can be used to remove the waste volume (e.g., supernatant liquid), and multiple aspirations by the pipetting system may be necessary to ensure as complete a removal of the supernatant as possible. In an example of the first variation, a 1000 micro liter pipette tip can be used to perform gross removal of the waste volume in a first aspiration followed by the use of a finer pipette tip (e.g., 100-200 microliter tip) in additional aspirations, to remove the remainder of the waste volume. In the example, the removal of the waste volume occurs close to the bottom of the process chamber to provide complete liquid removal with minimal bubbling. In a second variation, the lysed moiety-sample solution can be transferred to a vessel that enables the moiety-bound nucleic acid volume to be captured and the waste volume to be removed in a flow through manner, either against the pores of a filter or in the presence of a magnetic field. In the second variation, the microparticles with bound nucleic acids are retained in a filter zone or a magnetic field zone of the vessel, and the liquid portion is flowed into a "waste chamber". In a specific example of the second variation, a system (such as the one described in U.S. patent application Ser. No. 13/766,359, entitled "System and Method for

Claim	Claim Language	Infringement Evidence
		<p>Processing and Detecting Nucleic Acids") can be used to transfer the lysed moiety-sample solution into a fluidic pathway of a cartridge (such as the one described in U.S. patent application Ser. No. 13/765,996, entitled "Microfluidic Cartridge for Processing and Detecting Nucleic Acids"). In the specific example, the lysed moiety-sample solution can be retained by a magnetic field within a portion of the fluidic pathway upon occlusion of the fluidic pathway at a suitable set of occlusion positions, in order to separate the moiety-bound nucleic acid volume from the waste volume. The waste volume can then be removed by pushing the waste volume to a waste chamber of the cartridge.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,382,532 at 24:1-14 “A first illustration of the eighteenth example, as shown in FIG. 22A, of a fluidic pathway 165 preferably comprises an initial segment 174 fluidically coupled to a fluid channel 119 coupled to a shared fluid port 118, a sample segment 175 coupled to a sample port 114 and to the initial segment 174, and an s-shaped capture segment 166, configured to pass through the heating region 195 and a magnetic field 156, coupled to the initial segment 174 and the sample segment 175. In an alternative illustration of the eighteenth example, 10 the s-shaped capture segment 166 may comprise an initial wide arc 166 to provide a greater surface area for magnetic bead capture. In another illustration of the eighteenth example, the capture segment 166 may alternatively be a progressively narrowing s-shaped capture segment 166.”) U.S. Patent No. 9,382,532 at FIG. 22A:  <p style="text-align: center;">FIGURE 22A</p> <ul style="list-style-type: none"> U.S. Patent No. 9,382,532 at 25:35-50 (“A volume of release solution will still be maintained within the capture segment 166 at this stage. The first and the fourth occlusion positions 142, 145 may then be occluded to form a sixth truncated pathway sealing the volume of release solution, with the captured magnetic beads bound to nucleic acids, within the capture segment 166. The volume of the remaining release solution is therefore substantially defined by the microchannel volume between junctions in the fluidic pathway 165 near the fourth and sixth occlusion positions 145, 147, and maybe any small volume

Claim	Claim Language	Infringement Evidence
		<p>but in a specific variation is precisely metered to be 23+/-1 microliters. Release solution may be sealed within capture segments of other fluidic pathways using a similar process. A heater may then be provided at the sixth truncated pathway, inducing a pH shift within the sixth truncated pathway to unbind nucleic acids from the magnetic beads.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,382,532 at 27:17-42 (“The occlusion positions of the set of occlusion positions 141' of the second illustration are preferably located such that occluding of subsets of the set of occlusion positions 141' defines unique truncated fluidic pathways to controllably direct fluid flow. For example, occluding the fluidic pathway 165' at the first, fourth, sixth, tenth, and eleventh occlusion positions 142', 145', 147', 158', 159' forms a truncated pathway by which a volume of a sample fluid, comprising nucleic acids bound to magnetic beads and delivered into the sample port 114, may flow into the capture segment 166' for isolation and purification of nucleic acids using the heating region 195 and the magnetic field 156. Nucleic acids bound to magnetic beads may thus be trapped within the capture segment 166' by the magnetic field 156, while other substances in the volume of sample fluid may pass into the waste chamber 130 by passing the fifth occlusion position 146'. Following this subset of occlusion positions, the occlusion at the first occlusion position 142' may be reversed, and the fluidic pathway 165' may be occluded at the second occlusion position 143' to form a second truncated pathway by which a wash fluid may be delivered through the fluid port 118, into the capture segment 166' (thus washing the trapped magnetic beads), and into the waste chamber 130 by passing the fifth occlusion position 146'. A volume of air may then be pumped through the fluid port 118 to flush any remaining wash solution into the waste chamber 130.”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct

Claim	Claim Language	Infringement Evidence
		<p>pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) • U.S. Patent No. 9,050,594 at 3:1-13 (“The system 100 thus functions to receive biological samples containing nucleic acids (i.e., impure nucleic acid samples), separate nucleic acids from the biological samples, and analyze nucleic acid samples according to at least one molecular diagnostic protocol (e.g., PCR). Preferably, the system 100 is a walkaway system by which a user loads a set of biological samples containing nucleic acids, and receives a set of data resulting from a molecular diagnostic protocol without any farther sample manipulation by the user. Alternatively, the system 100 facilitates aspects of sample preparation for a molecular diagnostic protocol, with some sample manipulation performed by the user.”) • U.S. Patent No. 9,050,594 at 3:20-33 (“The liquid handling system 250 then aspirates substantially all of each sample of the set of lysed biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate no [sic], and dispenses the set of magnetic bead samples into a microfluidic cartridge 210, aligned within a cartridge receiving module 140 of a molecular diagnostic module 130, and configured to be manipulated by the molecular diagnostic module 130. A heating and cooling subsystem 150, a magnet 160, and a valve actuation subsystem 170 of the molecular diagnostic module 130 then facilitate separation of a set of nucleic acids from the magnetic bead-samples, as the liquid handling system 250 dispenses wash solutions, release solutions, and/or air at appropriate stages.”) • U.S. Patent No. 9,050,594 at FIG. 7A

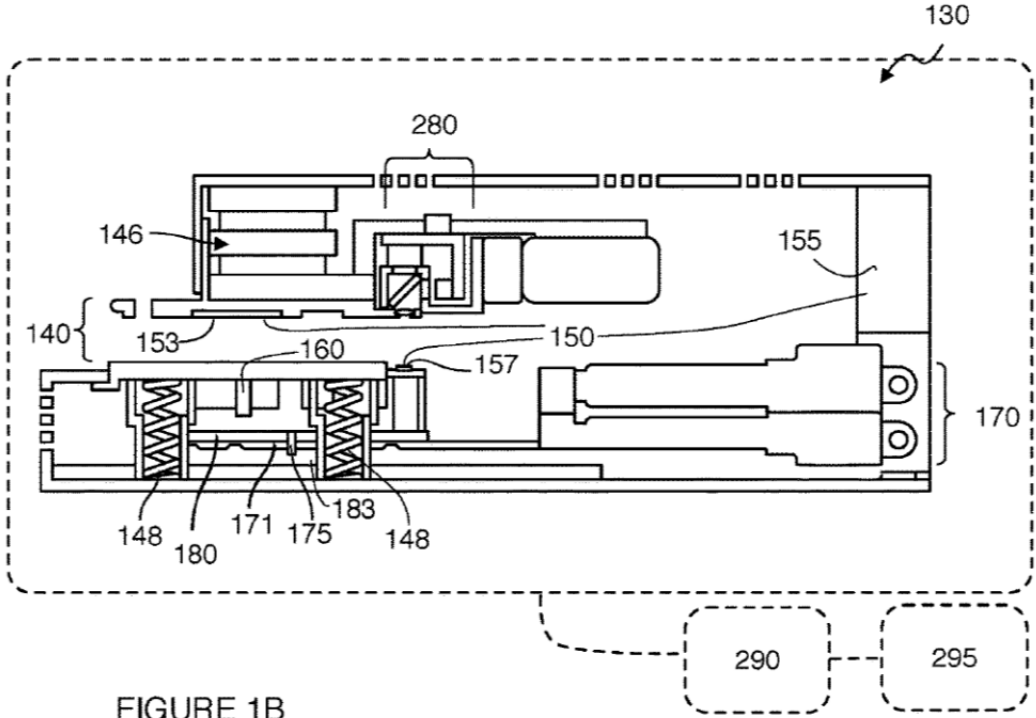
Claim	Claim Language	Infringement Evidence
		 <p style="text-align: center;">FIG. 7A</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 4:45-49 (“Additionally, the magnetic beads may be treated to be positively charged. However, the magnetic beads may alternatively be any appropriate magnetic beads (e.g. magnetic, paramagnetic [sic], or superparamagnetic) configured to facilitate biomagnetic separation.”) • U.S. Patent No. 9,050,594 at 10:49-65 (“The cartridge heater 153 functions to transfer heat to a heating region 224 of a microfluidic cartridge 210, for inducing a pH shift to release bound nucleic acids from magnetic beads within the heating region 224. The cartridge heater 153 is preferably a plate-shaped heater configured to transfer heat to the microfluidic cartridge 210 only from one side of the cartridge heater 153, such that heat flows through one face of the plate-shaped heater to the microfluidic cartridge 210. In a specific example, the cartridge heater 153 is a silicon wafer etched to be conductive and form a resistance heater. In the preferred variation, the cartridge heater 153 is either flip-chip bonded (i.e., soldered to back side of a circuit board), or wire bonded to a circuit board, and then coupled using linear bearings and springs to a plate coupled to the linear actuator 146. The preferred variation allows independent control of 12 independent channels, corresponding to 12 different pathways for sample processing.”) • U.S. Patent No. 9,050,594 at 12:64-13:1 (“The magnet 160 of the molecular diagnostic module 130 functions to provide a magnetic field for isolation and extraction of nucleic acids bound to magnetic beads within a microfluidic cartridge 210, aligned within the molecular diagnostic module 130.”) • U.S. Patent No. 9,050,594 at 13:51-54 (“Alternative configurations and/or compositions of the magnet 160 may also be appropriate in facilitating isolation and extraction of nucleic acids bound to magnetic

Claim	Claim Language	Infringement Evidence
		<p>beads within the microfluidic cartridge 210.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 19:28-43 (“As described above, alternative embodiments of the molecular diagnostic module 130 and alternative variations of subsystems and elements of the molecular diagnostic module 130 may be configured to process a biological sample containing nucleic acids, isolate nucleic acids from the biological sample, and detect nucleic acids. An example of an alternative embodiment of a molecular diagnostic module 130, as shown in FIG. 13, includes a cartridge receiving module 140’, a heating and cooling subsystem 150’, a magnet 160’, a valve actuation subsystem 170’, and an optical subsystem 180’, and functions to manipulate an alternative microfluidic cartridge 210’ for processing of biological samples containing nucleic acids. Other alternative embodiments of the molecular diagnostic module 130” may be configured to receive alternative microfluidic cartridges 210”, for processing of biological samples containing nucleic acids.”) • U.S. Patent No. 9,050,594 at 22:29-33 (“The microfluidic cartridge 210 functions to receive a set of magnetic bead-samples, facilitate separation of nucleic acids from the set of magnetic bead-samples, receive a set of nucleic acid-reagent samples, and facilitate analysis of nucleic acids from the set of nucleic acid-reagent samples”) • U.S. Patent No. 9,050,594 at 22:61-23:5 (“The microfluidic cartridge 210 is preferably configured to be received and manipulated by the molecular diagnostic module 130, such that the cartridge receiving module 140 of the molecular diagnostic module 130 receives and aligns the microfluidic cartridge 210 within the molecular diagnostic module 130, the heating and cooling subsystem 150 of the molecular diagnostic module 130 is configured to transfer heat to the heating region 224 of the microfluidic cartridge 210, and the magnet 160 of the molecular diagnostic module 130 is configured to be received by the magnet housing region 218 of the microfluidic cartridge 210 to provide a magnetic field for separation of nucleic acids.”) • U.S. Patent No. 9,050,594 at 23:28-58 (“The liquid handling system 250 of the system 100 includes a liquid handling arm 255 and a syringe pump 265, as shown in FIGS. 14A-14C and functions to deliver biological samples, reagents, and gases to elements of the system 100. As described in Section 1, an embodiment of the liquid handling system 250 is configured to aspirate a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), dispense the set of biological samples into a capture plate no to be lysed and combined with magnetic beads by a capture plate module 120, aspirate the set of biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate 110, and dispense the set of magnetic bead-samples into microfluidic cartridge 210 located in a molecular diagnostic module 130. The embodiment of the liquid handling system 100 is

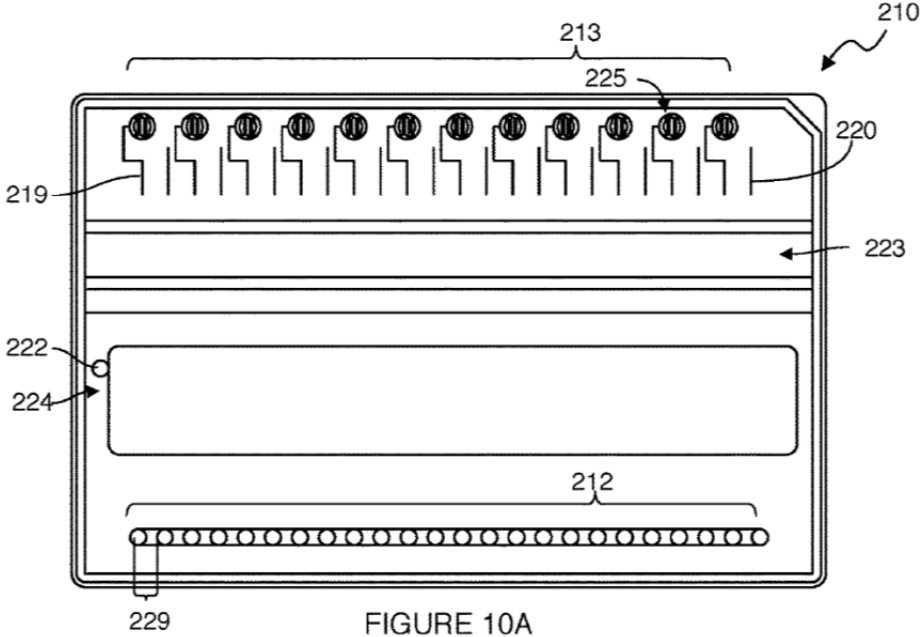
Claim	Claim Language	Infringement Evidence
		<p>further configured to facilitate separation of a set of nucleic acids from the magnetic bead-samples, by dispensing a wash solution, a release solution, and/or air into the molecular diagnostic module 130, by the nozzle 149 coupled to the linear actuator 146, at appropriate stages, aspirate the set of nucleic acids from the molecular diagnostic module 130, combine the set of nucleic acids with a set of molecular diagnostic reagents using an assay strip 190, and dispense the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the molecular diagnostic module 130 for further processing and analysis. [Other embodiments of the liquid handling system 250 may be configured to perform alternative molecular diagnostic assay protocols and/or dispense and aspirate alternative fluids into and from other elements supporting a molecular diagnostic protocol.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 27:2-13 (“An embodiment of a method 400 for processing and detecting nucleic acids from a set of biological samples comprises: combining each biological sample of the set of biological samples with a quantity of magnetic beads to produce a set of magnetic bead-sample mixtures S410; heating the set of magnetic bead-sample mixtures to produce a set of nucleic acid-magnetic bead samples S420; transferring each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways S430; producing a set of nucleic acid volumes from the set of nucleic acid-magnetic bead samples S440”) • U.S. Patent No. 9,050,594 at 28:53-29:4 (“Step S430 recites transferring each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways, and functions to isolate each of the set of nucleic acid-magnetic bead samples within separate pathways for further processing. Preferably, all nucleic acid-magnetic bead samples in the set of nucleic acid-magnetic bead samples are transferred simultaneously to the set of fluidic pathways, but alternatively, each nucleic acid-magnetic bead sample in the set of magnetic bead-samples may be transferred to a corresponding fluidic pathway independently of the other nucleic acid-magnetic bead samples. In addition, preferably the entire volume, or substantially all of the volume, of the nucleic acid-magnetic bead sample is transferred to the set of fluidic pathways, without magnetically isolating magnetic beads and removing supernatant fluids prior to transferring each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways.”) • U.S. Patent No. 9,050,594 at 29:27-50 (“Step S440 recites producing a set of nucleic acid volumes from the set of nucleic acid-magnetic bead samples, and functions to separate nucleic acid volumes from the set of nucleic acid-magnetic bead samples. Step S440 preferably reduces a concentration of unwanted

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		<p>matter from the set of biological samples being processed, to an acceptable level; however, Step S440 may alternatively entirely remove substantially all unwanted substances from the set of biological samples being processed. Step S440 preferably includes providing a magnetic field S441, such that each fluidic pathway in the set of fluidic pathways is configured to cross the magnetic field. Preferably, the set of nucleic acid-magnetic bead samples is captured and isolated within portions of the set of fluidic pathways crossing the magnetic field. Step S440 may further comprise providing a heater configured to span a heating region of the set of fluidic pathways S442, but may alternatively comprise providing multiple heaters or altogether omit providing a heater. In embodiments wherein multiple heaters are provided, each heater is preferably independent to allow independent control of heating time and temperature for each sample. Step S442 functions to provide a heater, which, in combination with a release solution that provides a pH shift, facilitate a rapid and efficient unbinding of the nucleic acids from magnetic beads.”)</p> <p>US10093963 (Exhibit 49)</p> <ul style="list-style-type: none"> • Claim 1. A system for processing and detecting nucleic acids using a cartridge with a fluidic pathway, the system comprising: a cartridge platform configured to receive the cartridge, the cartridge platform comprising an access region configured to align with the fluidic pathway; a valve actuation subsystem comprising: a pin comprising a first end, a second end, and a displacement region, the pin actuatable along a displacement axis extending through the first end, the second end, and the access region; a spring, coupled to the displacement region of the pin, that biases the pin along the displacement axis; and an actuation substrate comprising a groove and a protrusion, the actuation substrate translatable along an actuation axis perpendicular to the displacement axis; wherein the system is operable between: a closed configuration, wherein the groove is aligned with the displacement region and the first end of the pin extends through the access region; and an open configuration, wherein the protrusion is aligned with the displacement region and the first end of the pin is displaced away from the access region. • U.S. Patent No. 10,093,963 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem including an actuation substrate, and a set of pins interacting with the actuation substrate, and a spring plate configured to bias at least one pin in a configurations, the valve actuation subsystem configured to control fluid flow through a microfluidic

Claim	Claim Language	Infringement Evidence
		<p>cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; and a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 10,093,963 at 2:24-53 (“As shown in FIGS. 1A-1B, an embodiment of a system 100 for processing biological samples includes: a molecular diagnostic module 130 comprising a microfluidic cartridge receiving module 140, heating and cooling subsystem 150, a magnet 160, a valve actuation subsystem 170, and an optical subsystem 280. Other embodiments of the system 100 can further comprise a microfluidic cartridge 210 configured to facilitate sample processing; a liquid handling system 250 configured to facilitate gas and fluid delivery to different elements of the system 100; a processor 290 configured to analyze data resulting from a run of the system 100; and a user interface 295 configured to allow a user to interact with the system 100. The system 100 can additionally or alternatively include any other suitable elements, as described in U.S. application Ser. No. 13/766,359 entitled “System and Method for Processing and Detecting Nucleic Acids” and filed on 13 Feb. 2013, which is incorporated herein in its entirety by this reference. The system 100 thus functions to receive biological samples containing nucleic acids (i.e., impure nucleic acid samples), separate nucleic acids from the biological samples, and analyze nucleic acid samples according to at least one molecular diagnostic protocol (e.g., PCR). Preferably, the system 100 is a walkaway system by which a user loads a set of biological samples containing nucleic acids, and receives a set of data resulting from a molecular diagnostic protocol without any further sample manipulation by the user. Alternatively, the system 100 facilitates aspects of sample preparation for a molecular diagnostic protocol, with some sample manipulation performed by the user.”) U.S. Patent No. 10,093,963 at FIG. 1B.

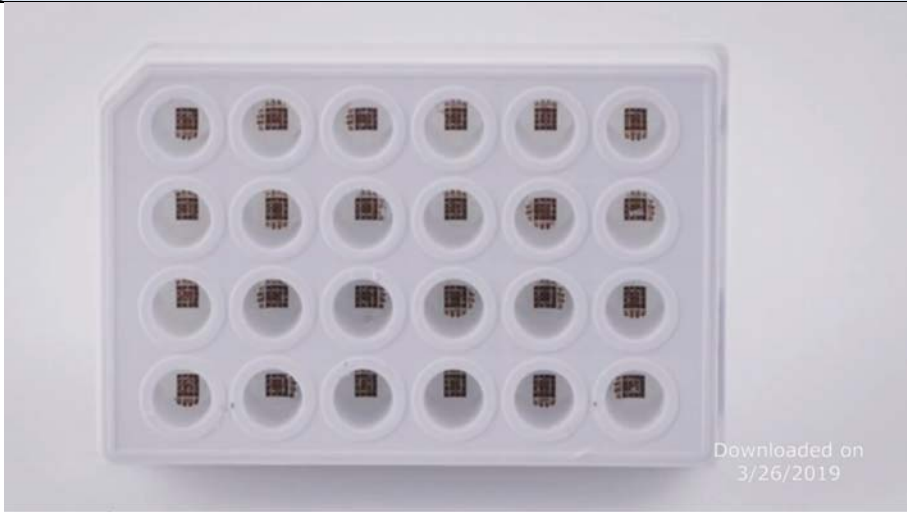
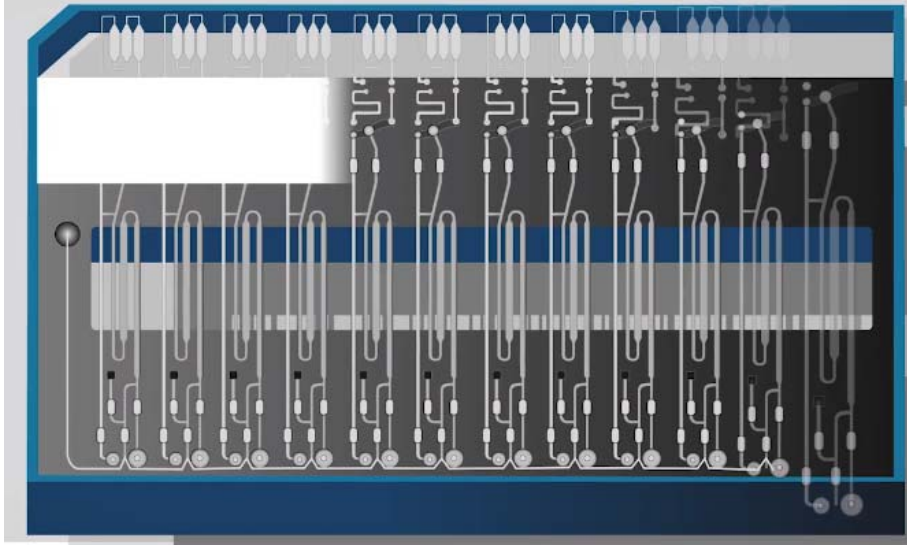
Claim	Claim Language	Infringement Evidence
		 <p data-bbox="779 927 951 959">FIGURE 1B</p> <ul data-bbox="615 976 2020 1409" style="list-style-type: none"> • U.S. Patent No. 10,093,963 at 2:54-65 (“In one example workflow of the system 100, a liquid handling system 250 aspirates a set of biological samples and dispenses the biological samples into a microfluidic cartridge 210, aligned within a cartridge receiving module 140 of a molecular diagnostic module 130, and configured to be manipulated by the molecular diagnostic module 130. A heating and cooling subsystem 150, a magnet 160, and a valve actuation subsystem 170 of the molecular diagnostic module 130 then facilitate separation of a set of nucleic acids from the biological samples, as the liquid handling system 250 dispenses wash solutions, release solutions, and/or air at appropriate stages.”) • U.S. Patent No. 10,093,963 at 15:40-16:5 (“The microfluidic cartridge 210 functions to receive a set of magnetic bead-samples, facilitate separation of nucleic acids from the set of magnetic bead-samples, receive a set of nucleic acid-reagent samples, and facilitate analysis of nucleic acids from the set of nucleic acid-reagent samples. In one embodiment, as shown in FIGS. 9A and 9B, the microfluidic cartridge 210 comprises a top layer 211 including a set of sample port-reagent port pairs 212 and a set of

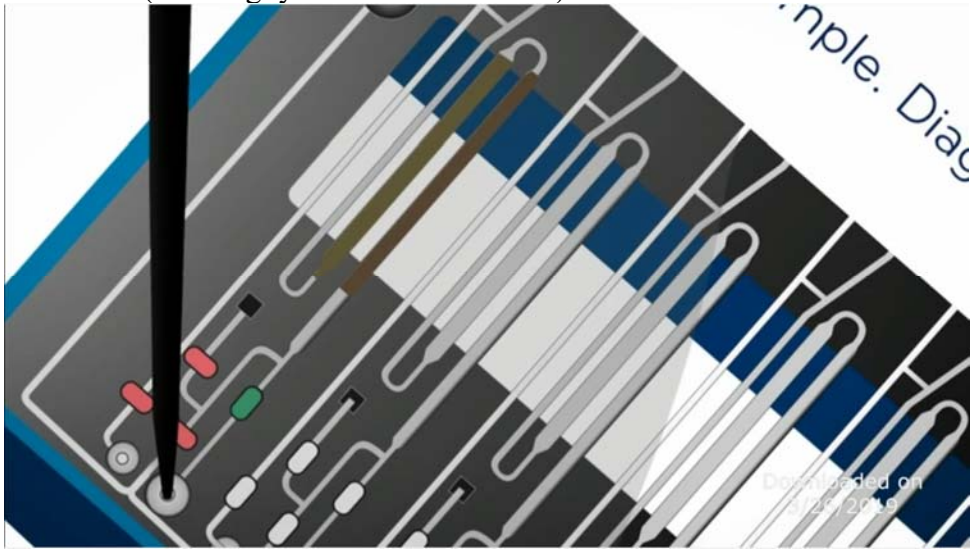
Claim	Claim Language	Infringement Evidence
		<p>detection chambers 213; an intermediate substrate 214, coupled to the top layer 211 and partially separated from the top layer 211 by a film layer 215, configured to form a waste chamber 216; an elastomeric layer 217 partially situated on the intermediate substrate 214; a magnet housing region 218 accessible by a magnet 160 providing a magnetic field; and a set of fluidic pathways 219, each formed by at least a portion of the top layer 211, a portion of the film layer 215, and a portion of the elastomeric layer 217. In the embodiment, the microfluidic cartridge 10 further comprises a bottom layer 221 coupled to the intermediate substrate 214 and configured to seal the waste chamber 216. Furthermore, in the embodiment, the top layer 211 of the microfluidic cartridge 210 further comprises a shared fluid port 222, a vent region 223, and a heating region 224, such that each fluidic pathway 220 in the set of fluidic pathways 219 is fluidically coupled to a sample port-reagent port pair 229, the shared fluid port 222, the waste chamber 216, and a detection chamber 225, comprises a turnabout portion configured to pass through the heating region 224 and the magnetic field, and is configured to pass through the vent region 223 upstream of the detection chamber 225. Each fluidic pathway 220 thus functions to receive and facilitate processing of a sample fluid containing nucleic acids as it passes through different portions of the fluidic pathway 220”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 10,093,963 at FIG. 10A.


Claim	Claim Language	Infringement Evidence
		 <p style="text-align: center;">FIGURE 10A</p> <ul style="list-style-type: none"> U.S. Patent No. 10,093,963 at 6:28-58 (“The magnet 160 of the molecular diagnostic module 130 functions to provide a magnetic field for isolation and extraction of nucleic acids bound to magnetic beads within a microfluidic cartridge 210, aligned within the molecular diagnostic module 130. Preferably, the magnet 160 is fixed within the molecular diagnostic module 130, such that the extended configuration 146 b of the linear actuator 146 allows the magnet 160 to pass through the magnet receiving slot 144 of the cartridge receiving module 140 and into a magnet housing region 218 of the microfluidic cartridge 210. In an example, the magnet 160 is a rectangular prism-shaped magnet 160 fixed under the cartridge platform 141, and configured to pass through the cartridge platform 141, into a magnet housing region 218 located under the heating region of the microfluidic cartridge 210. Preferably, the magnet 160 is one of two or three magnets lined up in parallel, such that each of the fluidic pathways of a microfluidic cartridge housing the magnets is exposed to two or three times as much magnetic flux, and two to three[sic] times as many opportunities to capture magnetic beads. Alternatively, the magnet 160 is a single magnet configured to expose a set of fluidic pathways to a magnetic field. Preferably, the magnet 160 or group of multiple magnets is coupled to a magnet holder within the molecular diagnostic module 130. Additionally, the magnet holder is preferably composed of an insulating material, such that the magnet


Claim	Claim Language	Infringement Evidence
		<p>holder does not interfere with proper functioning of the cartridge heater 153. Alternatively, the magnet holder may not be composed of an insulating material.”)</p> <ul style="list-style-type: none"> <p>U.S. Patent No. 10,093,963 at 16:6-17 (“The microfluidic cartridge 210 is preferably configured to be received and manipulated by the molecular diagnostic module 130, such that the cartridge receiving module 140 of the molecular diagnostic module 130 receives and aligns the microfluidic cartridge 210 within the molecular diagnostic module 130, the heating and cooling subsystem 150 of the molecular diagnostic module 130 is configured to transfer heat to the heating region 224 of the microfluidic cartridge 210, and the magnet 160 of the molecular diagnostic module 130 is configured to be received by the magnet housing region 218 of the microfluidic cartridge 210 to provide a magnetic field for separation of nucleic acids.”)</p> <p>U.S. Patent No. 10,093,963 at 16:40-65 (“The liquid handling system 250 of the system 100 includes a liquid handling arm 255 and a syringe pump 265, as shown in FIGS. 10A-10C and functions to deliver biological samples, reagents, and gases to elements of the system 100. As described in Section 1, an embodiment of the liquid handling system 250 is configured to aspirate a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), and dispense the set of biological samples into microfluidic cartridge 210 located in a molecular diagnostic module 130. The embodiment of the liquid handling system 100 is further configured to facilitate separation of a set of nucleic acids from the magnetic bead-samples, by dispensing a wash solution, a release solution, and/or air into the molecular diagnostic module 130, by the nozzle 149 coupled to the linear actuator 146, at appropriate stages, aspirate the set of nucleic acids from the molecular diagnostic module 130, combine the set of nucleic acids with a set of molecular diagnostic reagents, and dispense the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the molecular diagnostic module 130 for further processing and analysis. Other embodiments of the liquid handling system 250 can be configured to perform alternative molecular diagnostic assay protocols and/or dispense and aspirate alternative fluids into and from other elements supporting a molecular diagnostic protocol.”)</p> <p>U.S. Patent No. 10,093,963 at 17:54-18:11 (“As shown in FIG. 11, an embodiment of a method 400 for processing and detecting nucleic acids from a set of biological samples comprises: producing a set of magnetic bead-sample mixtures from the set of biological samples S410; heating the set of magnetic bead-sample mixtures to produce a set of nucleic acid-magnetic bead samples S420; transferring each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways S430; producing a set of nucleic acid</p>


Claim	Claim Language	Infringement Evidence
		<p>volumes from the set of nucleic acid-magnetic bead samples S440; combining each nucleic acid volume of the set of nucleic acid volumes with a molecular diagnostic reagent of a set of molecular diagnostic reagents to produce a set of nucleic acid-reagent mixtures S450; transferring each of the set of nucleic acid-reagent mixtures, through the corresponding fluidic pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers S460; and receiving light from the set of nucleic acid-reagent mixtures S470. The method 400 can further include generating a set of data based on light received from the set of nucleic acid-reagent mixtures S480. The method 400 functions to isolate and extract a set of nucleic acid volumes from a biological sample, and to facilitate analysis of the nucleic acid volumes according to at least one molecular diagnostic protocol.”)</p>
1(c)	the first module comprising, a plurality of sample tubes in the first module, each sample tube configured to accept a nucleic acid-containing sample of the plurality of nucleic-acid containing samples	<p>In the accused system, the first module comprises, a plurality of sample tubes in the first module, each sample tube configured to accept a nucleic acid-containing sample of the plurality of nucleic-acid containing samples.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “Liquid Handling Processing A: Lysis and Capture. Dispensing lysis buffer. Dispensing lysis buffer and patient specimen into extraction plate. The liquid handling robot delivers lysis buffer and patient specimen to the extraction plate, which has 24 independent wells which contain NeuDry affinity-coated paramagnetic beads. Each mixture is aspirated and dispensed five times to ensure homogeneity of the solution. During the transfer of patient specimen to the extraction plate the liquid handling robot uses pre-defined no-fly zones to reduce the potential of contamination.” <i>Id.</i> at 0:28-1:05 • <i>Id.</i> at 0:40 (showing the extraction plate).

Claim	Claim Language	Infringement Evidence
		<div data-bbox="661 228 1562 737">  </div> <ul style="list-style-type: none"> <p>“This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59</p> <div data-bbox="661 818 1562 1360">  </div> <ul style="list-style-type: none"> <p>“The liquid handling robot employs total aspiration and dispense monitoring pressure sensing to ensure</p>

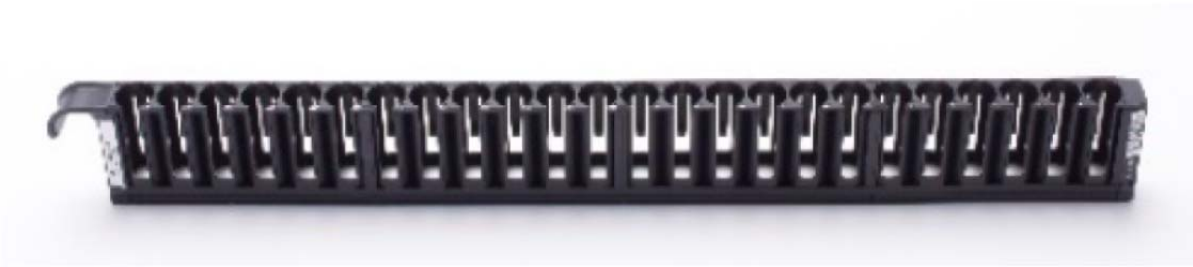

Claim	Claim Language	Infringement Evidence
		<p>each tip is securely seated into one of the 12 independent sample ports or s-ports of the cartridge. Once the pipette tip is secured, the entire volume of solution will be dispensed.” <i>Id.</i> at 2:02-2:07</p> <ul style="list-style-type: none"> • “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” <i>Id.</i> at 2:24-2:28 • <i>Id.</i> at 2:28 (showing lysate in the s-channel).  <p><i>NeuMoDx Molecular N288 System</i>, http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ TECHNOLOGY” hyperlink at https://player.vimeo.com/video/281470603. (Exhibit 17)</p> <ul style="list-style-type: none"> • At 0:20 (showing patient sample tubes)

Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none">• At 3:10 (showing a liquid dispenser at a sample tube)

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		 <ul style="list-style-type: none">At 4:17 (showing a liquid dispenser at a multi-lane microfluidic cartridge aligned in a receiving bay)

Claim	Claim Language	Infringement Evidence
		 <p>NeuMoDx_288_Spec_Sheet_R2 (Exhibit 22)</p> <ul style="list-style-type: none"> • “Simultaneous use of multiple tube types and sizes.” <i>Id.</i> at 1. • “Flexible specimen tube compatibility: Diameter: 11 mm - 18 mm, Height: 60 mm – 120 mm” <i>Id.</i> <p>JFO_2018-10-25-8009-Rev-B_NeuMoDx-96-Spec-Sheet (Exhibit 21)</p> <ul style="list-style-type: none"> • “Simultaneous use of multiple tube types and sizes.” <i>Id.</i> at 1. • “Flexible specimen tube compatibility: Diameter: 11 mm - 18 mm, Height: 60 mm – 120 mm” <i>Id.</i> <p>40600129_D-IFU-GBS-Test-Strip-US-only (Exhibit 60)</p> <ul style="list-style-type: none"> • “Other Equipment and Materials Required But Not Provided . . . 4. Specimen Tubes compatible with the NeuMoDx System (See Test Preparation for details).” <i>Id.</i> at p. 2. • “Test Preparation <ol style="list-style-type: none"> 1. Apply specimen barcode label to a specimen tube compatible with the NeuMoDx System. 2. Gently vortex the enriched broth specimen to achieve uniform distribution. 3. Using a transfer pipette, transfer ≥ 1 mL of Lim broth to the barcoded specimen (daughter) tube.

Claim	Claim Language	Infringement Evidence
		<p>Use a different transfer pipette for each specimen. The daughter tube must meet the following tube specifications compatible with the NeuMoDx System based on Specimen Tube Carrier being used for processing.</p> <ul style="list-style-type: none"> • 32-Tube Carrier: between 11 mm – 14 mm in diameter and between 60 mm and 120 mm in height • 24-Tube Carrier: between 14.5 mm – 18 mm in diameter and between 60 mm and 120 mm in height” <i>Id.</i> at p. 4. <ul style="list-style-type: none"> • “NeuMoDx™ 288 Molecular System Operation . . . 4. Load the specimen tube(s) into a standard 32-Tube carrier or 24-Tube Carrier, and ensure caps are removed from all specimen tubes. 5. Place the Specimen Tube carrier on the Autoloader shelf and use the touchscreen to load carrier into the system. This will initiate processing of test(s).” <i>Id.</i> <p>400600146_D-IFU-NeuMoDx-LDT-Master-Mix-RNA-US-ONLY (Exhibit 62)</p> <ul style="list-style-type: none"> • “Sample Preparation <ol style="list-style-type: none"> 1. Apply a specimen barcode label to the desired specimen tube. If using a daughter tube, the daughter tube must meet the tube specifications compatible with the NeuMoDx System. The primary tube may also be used on the NeuMoDx System, if compatible and meets tube specifications. For additional details, see the NeuMoDx™ 288/96 Molecular System Operator’s Manual(s). 2. Gently vortex the specimen to achieve uniform distribution. 3. Use a transfer pipette to transfer 1-3 mL of specimen to a barcoded specimen tube compatible with the NeuMoDx System. Use a different transfer pipette for each specimen. 4. After ensuring all caps have been removed from the specimen tubes, load the barcoded specimen tubes into the appropriate Specimen Tube Carrier of the NeuMoDx System.” <i>Id.</i> at p. 3. • “NeuMoDx™ Molecular System Operation . . . 8. Load the specimen tube(s) into the appropriate Specimen Tube carrier, and ensure caps are removed from all specimen tubes. 9. Place Specimen Tube carrier on the Autoloader shelf and use the touchscreen to load carrier into the NeuMoDx System. This will initiate processing of test(s).” <i>Id.</i> at pp. 3-7. <p>40600145_-Rev-D-IFU-NeuMoDx-LDT-Master-Mix-DNA-US-ONLY-FINAL-25Oct2018 (Exhibit 67)</p> <ul style="list-style-type: none"> • “Sample Preparation <ol style="list-style-type: none"> 1. Apply a specimen barcode label to the desired specimen tube. If using a daughter tube, the daughter tube must meet the tube specifications compatible with the NeuMoDx System. The primary tube may also be used on the NeuMoDx System, if compatible and meets tube specifications. For

Claim	Claim Language	Infringement Evidence
		<p>additional details, see the NeuMoDx 288/96 Molecular System Operator's Manual(s).</p> <p>2. Gently vortex the specimen to achieve uniform distribution.</p> <p>3. Use a transfer pipette to transfer 1-3 mL of specimen to a barcoded specimen tube compatible with the NeuMoDx System. Use a different transfer pipette for each specimen.</p> <p>4. After ensuring all caps have been removed from the specimen tubes, load the barcoded specimen tubes into the appropriate Specimen Tube Carrier of the NeuMoDx System.” <i>Id.</i> at p. 3.</p> <ul style="list-style-type: none"> • “NeuMoDx System Operation . . . 8. Insert the specimen tube(s) into the appropriate Specimen Tube carrier, and ensure caps are removed from all specimen tubes. 9. Place Specimen Tube carrier on the Autoloader shelf and use the touchscreen to load carrier into the NeuMoDx System. This will initiate processing of test(s).” <i>Id.</i> at pp. 3-4. <p><i>Sample Tube Carrier (24 Tube) – NeuMoDx</i> https://www.neumodx.com/product/sample-tube-carrier-24-tube-173400/ (Exhibit 84)</p>  <p><i>Sample Tube Carrier (32 Tube) – NeuMoDx</i> https://www.neumodx.com/product/sample-tube-carrier-32-tube-173410/ (Exhibit 85)</p>  <p>40600094 D-IFU-NeuMoDx-Cartridge-US-ONLY (Exhibit 19)</p>

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • “The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx™ lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres.” • “The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound nucleic acid is eluted using the NeuMoDx™ RELEASE Solution.” <i>Id.</i> <p>9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 2:49-53 (“As shown in FIGS. 1A-1B and 7A, an embodiment of a system 100 for processing and detecting nucleic acids comprises: a capture plate 110 configured to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119; a molecular diagnostic module 130 comprising a microfluidic cartridge receiving module 140, heating and cooling subsystem 150, a magnet 160, a valve actuation subsystem 170, an optical subsystem 180; and an assay strip 190 configured to facilitate mixing of molecular diagnostic reagents with a nucleic acid volume.”) • U.S. Patent No. 9,050,594 at FIG. 1A.

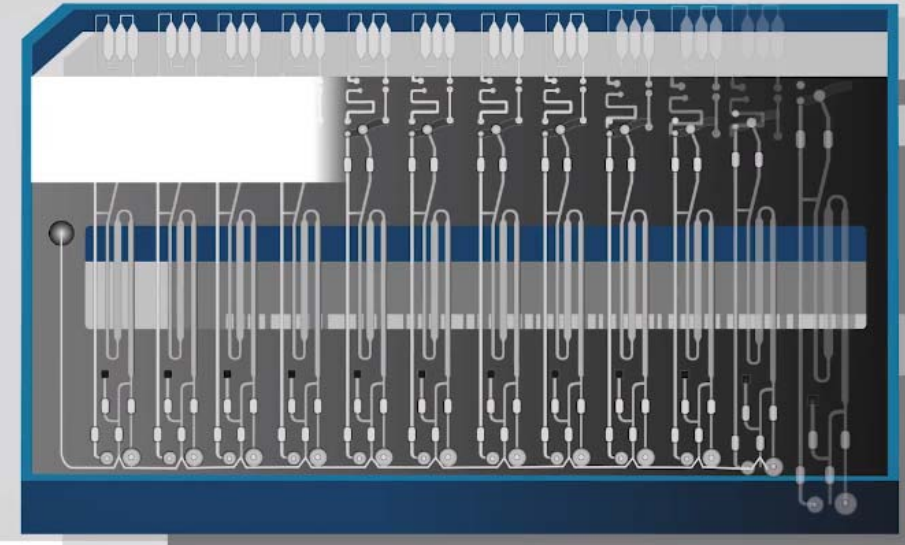
Claim	Claim Language	Infringement Evidence
		<p style="text-align: center;">FIG. 1A</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 3:14-20 (“In one example workflow of the system 100, a liquid handling system 250 aspirates a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), and dispenses the set of biological samples into a capture plate 110 to be lysed and combined with magnetic beads (containing a proprietary affinity coating to bind the nucleic acids to the magnetic beads) by a capture plate module 120.”)


Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 27:27-41 (“Step S410 recites combining each biological sample of the set of biological samples with a quantity of magnetic beads to produce a set of magnetic bead-sample mixtures, and functions to prepare a set of biological samples to be lysed and 30 combined with magnetic beads. For each biological sample, Step S410 preferably comprises aspirating a portion of the volume of the biological sample from a sample container (possibly containing an aqueous solution prior to addition of biological sample), and transferring the portion of the biological sample to a well containing a set of magnetic beads. Alternatively, for each biological sample, Step S410 may comprise aspirating the entire volume of the biological sample from a sample container, and transferring the volume of the biological sample to be combined with a set of magnetic beads.”) U.S. Patent No. 9,050,594 at 27:65-28:19 (“In a first variation of Step S410 for one biological sample, as shown in FIG. 16A, a volume of the biological sample is aspirated and combined with a set of magnetic beads. In the first variation of Step S410, a set of different biological samples may thus be aspirated simultaneously, and each biological sample may be transferred to an individual well to be combined with a set of magnetic beads to produce a set of magnetic bead-sample mixtures. In the first variation of Step S410, all magnetic bead-sample mixtures in the set of magnetic bead-sample mixtures are substantially non-identical in composition. In a second variation of Step S410, as shown in FIG.16B, a volume of a stock biological sample is aspirated, and portions of the volume of the stock biological sample are transferred to multiple wells to be combined with multiple sets of magnetic beads to produce a set of magnetic bead-sample mixtures. In the second variation of Step S410, all magnetic bead-sample mixtures in the set of magnetic bead-sample mixtures are substantially identical in composition. Other variations of Step S410 may comprise filtering at least one biological sample of the set of biological samples S415 prior to combining each biological sample of the set of biological samples with a quantity of magnetic beads.”) <p>US9382532 (exhibit 52)</p> <ul style="list-style-type: none"> Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of

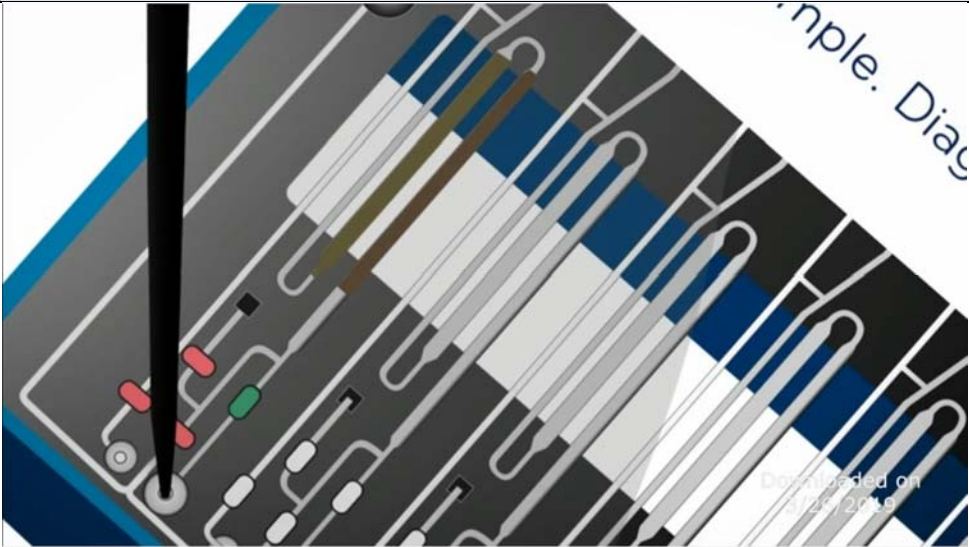
Claim	Claim Language	Infringement Evidence
		<p>moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 6. The method of claim 5, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety-sample mixture from the process chamber; occluding the fluidic pathway of the cartridge-at a set of occlusion positions upon displacement of pins of the set of pins to generate a path through a magnetic field, and to a waste chamber; and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber. • Claim 10. The method of claim 3, wherein washing the set of moiety-bound nucleic acid particles comprises aspirating the moiety-sample mixture; receiving the cartridge at the cartridge receiving module comprising the set of pins and a cam card interfacing with the set of pins; transitioning the cartridge to an active configuration that disposes the cartridge proximal the set of pins; displacing the first subset of the set of pins in the active configuration of the cartridge, upon translation of the cam card relative to the set of pins, thereby occluding the fluidic pathway of the cartridge at a set of occlusion positions; delivering the moiety-sample mixture into the fluidic pathway, wherein the fluidic pathway is configured to pass through a magnetic field and is coupled to a waste chamber, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field; and delivering a wash solution through the fluidic pathway and into the waste chamber in a continuous flow operation. • Claim 13. The method of claim 3, wherein releasing the nucleic acid sample from the set of moiety-bound nucleic acid particles comprises occluding the fluidic pathway of the cartridge, comprising the process chamber, at a set of occlusion positions, upon displacement of pins of the set of pins, to define a path through a magnetic field; delivering the set of moiety-bound nucleic acid particles into the path of the fluidic pathway; and delivering an elution solution into the fluidic pathway, thereby inducing a pH shift


Claim	Claim Language	Infringement Evidence
		<p>configured to release the nucleic acid sample from the set of moiety-bound nucleic acid particles.</p> <ul style="list-style-type: none"> • Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second subset of the set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction. • Claim 18. The method of claim 17, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety-sample mixture from the process chamber; occluding the fluidic pathway of the cartridge at a set of occlusion positions upon displacement of the first subset of the set of pins to generate a path through a magnetic field, and to a waste chamber of the cartridge; and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber. • Claim 19. A method for nucleic acid isolation from a biological sample, comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution includes a set of affinity moiety-coated microparticles, comprising a set of microparticles amide-bonded to at least one of Poly(allylamine) of molecular weight <30,000 Da and Polypropylenimine tetramine dendrimer Generation 1; producing a moiety-sample mixture upon combination of the binding moiety solution with the biological sample; producing a set of moiety-bound nucleic acid particles upon incubation of the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of


Claim	Claim Language	Infringement Evidence
		<p>affinity moiety-coated microparticles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of the set of pins includes reversing displacement of at least one pin of the first subset of the set of pins, and reversing occlusion of a portion of the fluidic pathway.</p>
1(d)	<p>a plurality of process chambers in the first module, wherein a process chamber of the plurality of process chambers is spatially separate from, and corresponds to, a sample tube of the plurality of sample tubes, the plurality of process chambers maintained at a same height relative to one another in the first module</p>	<p>In the accused system, the first module comprises, a plurality of process chambers in the first module, wherein a process chamber of the plurality of process chambers is spatially separate from, and corresponds to, a sample tube of the plurality of sample tubes, the plurality of process chambers maintained at a same height relative to one another in the first module.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “Liquid Handling Processing A: Lysis and Capture. Dispensing lysis buffer. Dispensing lysis buffer and patient specimen into extraction plate. The liquid handling robot delivers lysis buffer and patient specimen to the extraction plate, which has 24 independent wells which contain NeuDry affinity-coated paramagnetic beads. Each mixture is aspirated and dispensed five times to ensure homogeneity of the solution. During the transfer of patient specimen to the extraction plate the liquid handling robot uses pre-defined no-fly zones to reduce the potential of contamination.” <i>Id.</i> at 0:28-0:40 • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59

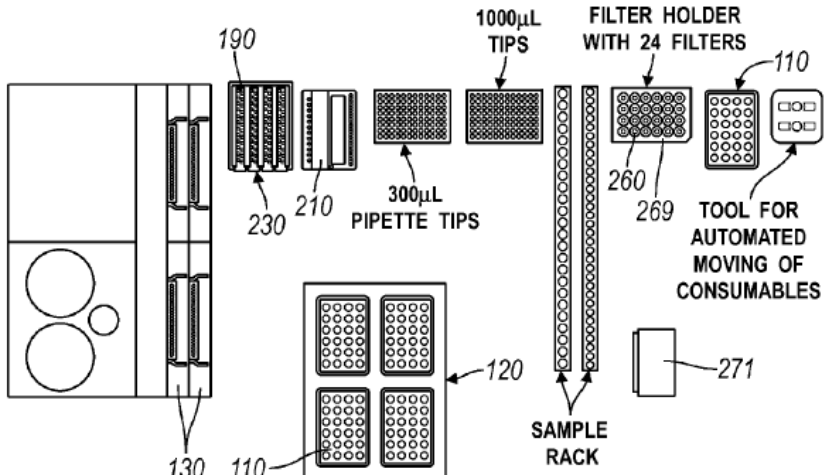
Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none"><li data-bbox="617 786 722 812">• 2:07

Claim	Claim Language	Infringement Evidence
		<div data-bbox="661 228 1906 927"></div> <ul style="list-style-type: none">• “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” <i>Id.</i> at 2:28-2:39.• <i>Id.</i> at 2:28 (showing lysate in the s-channel).

Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none"> • “A precise volume of air is then applied to remove any remaining liquid into the waste chamber. NeuMoDx wash solution is pumped via the fluid port into the microfluidic cartridge to remove all unbound material, followed by another volume of air to remove excess wash solution. High pH NeuMoDx release reagent is dispensed into the s-channel to cover the beads, and heat is applied to the denaturation process, resulting in released nucleic acid or eluate.” <i>Id.</i> at 2:39-3:12. <p><i>NeuMoDx Molecular N288 System</i>, http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ TECHNOLOGY” hyperlink at https://player.vimeo.com/video/281470603. (Exhibit 17)</p> <ul style="list-style-type: none"> • At 3:10 (showing al liquid dispenser at a sample tube)

Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none">• At 4:17 (showing a liquid dispenser at a multi-lane microfluidic cartridge aligned in a receiving bay)

Claim	Claim Language	Infringement Evidence
		 <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY (Exhibit 19)</p> <ul style="list-style-type: none"> • “The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx™ lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres.” • “The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound nucleic acid is eluted using the NeuMoDx™ RELEASE Solution.” <i>Id.</i> <p>US9441219 (Exhibit 53)</p> <ul style="list-style-type: none"> • U.S. 9,441,219 at 26:38-50 (“The system 100 may further comprise a tag reader 271, which functions

Claim	Claim Language	Infringement Evidence
		<p>to read barcodes, QR codes and/or any other identifying tags of the system 100. Preferably, the tag reader 271 is coupled to the liquid handling system 250, such that the tag reader 271 is configured to read tags on puncturable foil seals 115, 195 or tags located on any element of the system 100 accessible by the liquid handling system 250; however, the tag reader 271 may alternatively not be coupled to the liquid handling system 250. In one alternative embodiment of the system 100, the tag reader 271 may be a standalone unit that is configured to be manipulated by a user to scan tags or labels located on elements of the system 100.”)</p> <ul style="list-style-type: none"> U.S. 9,441,219 FIG. 2A  <p style="text-align: center;">FIG. 2A</p> <p>US9339812 (Exhibit 26)</p> <ul style="list-style-type: none"> U.S. 9,339,812 at 26:2-14 (“The system 100 may further comprise a tag reader 271, which functions to read barcodes, QR codes and/or any other identifying tags of the system 100. Preferably, the tag reader 271 is coupled to the liquid handling system 250, such that the tag reader 271 is configured to read tags on puncturable foil seals 115, 195 or tags located on any element of the system 100 accessible by the liquid handling system 250; however, the tag reader 271 may alternatively not be

Claim	Claim Language	Infringement Evidence
		<p>coupled to the liquid handling system 250. In one alternative embodiment of the system 100, the tag reader 271 may be a standalone unit that is configured to be manipulated by a user to scan tags or labels located on elements of the system 100.”)</p> <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> U.S. 9,050,594 at 26:1-12 (“The system 100 may further comprise a tag reader 271, which functions to read barcodes, QR codes and/or any other identifying tags of the system 100. Preferably, the tag reader 271 is coupled to the liquid handling system 250, such that the tag reader 271 is configured to read tags on puncturable foil seals 115, 195 or tags located on any element of the system 100 accessible by the liquid handling system 250; however, the tag reader 271 may alternatively not be coupled to the liquid handling system 250. In one alternative embodiment of the system 100, the tag reader 271 may be a standalone unit that is configured to be manipulated by a user to scan tags or labels located on elements of the system 100.”) <p>US9452430 (Exhibit 56)</p> <ul style="list-style-type: none"> U.S. 9,452,430 at 22:35 (“Other embodiments of the microfluidic cartridge 100 may further comprise a tag 198 that functions to encode and provide identifying information related to the microfluidic cartridge 100. The tag 198 may comprise a barcode, QR code, or other optical machine-readable tag, or may alternatively be an electronic tag, such as an RFID chip. The identifying information preferably comprises at least information relating to the position of a microfluidic cartridge 100 within a molecular diagnostic system, and information relating to samples analyzed using the microfluidic cartridge 100 (e.g. how many positions remain available for conducting tests). In alternative variations, the tag may relate other information about samples (e.g. sample type, Sample Volume, Sample concentration, date) processed using the microfluidic cartridge 100.”) <p>US9433940 (Exhibit 57)</p> <ul style="list-style-type: none"> U.S. 9,433,940 at 22:27-38 (“Other embodiments of the microfluidic cartridge 100 may further comprise a tag 198 that functions to encode and provide identifying information related to the microfluidic cartridge 100. The tag 198 may comprise a barcode, QR code, or other optical machine-readable tag, or may alternatively be an electronic tag, such as an RFID chip. The identifying information preferably comprises at least information relating to the position of a microfluidic cartridge 100 within a molecular diagnostic system, and information relating to samples analyzed using the microfluidic

Claim	Claim Language	Infringement Evidence
		<p>cartridge 100 (e.g. how many positions remain available for conducting tests).”)</p> <p>US9382532 (exhibit 52)</p> <ul style="list-style-type: none"> • Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10. • Claim 5. The method of claim 3, wherein separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture. • Claim 6. The method of claim 5, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety-sample mixture from the process chamber; occluding the fluidic pathway of the cartridge-at a set of occlusion positions upon displacement of pins of the set of pins to generate a path through a magnetic field, and to a waste chamber; and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber. • Claim 10. The method of claim 3, wherein washing the set of moiety-bound nucleic acid particles comprises aspirating the moiety-sample mixture; receiving the cartridge at the cartridge receiving module

Claim	Claim Language	Infringement Evidence
		<p>comprising the set of pins and a cam card interfacing with the set of pins; transitioning the cartridge to an active configuration that disposes the cartridge proximal the set of pins; displacing the first subset of the set of pins in the active configuration of the cartridge, upon translation of the cam card relative to the set of pins, thereby occluding the fluidic pathway of the cartridge at a set of occlusion positions; delivering the moiety-sample mixture into the fluidic pathway, wherein the fluidic pathway is configured to pass through a magnetic field and is coupled to a waste chamber, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field; and delivering a wash solution through the fluidic pathway and into the waste chamber in a continuous flow operation.</p> <ul style="list-style-type: none"> • Claim 11. The method of claim 1, wherein washing the set of moiety-bound nucleic acid particles comprises transferring the moiety-sample mixture to a fluid vessel, capturing the set of moiety-bound nucleic acid particles within the fluid vessel, and washing the set of moiety-bound nucleic acid particles using a series of aspiration and dispensing steps. • Claim 13. The method of claim 3, wherein releasing the nucleic acid sample from the set of moiety-bound nucleic acid particles comprises occluding the fluidic pathway of the cartridge, comprising the process chamber, at a set of occlusion positions, upon displacement of pins of the set of pins, to define a path through a magnetic field; delivering the set of moiety-bound nucleic acid particles into the path of the fluidic pathway; and delivering an elution solution into the fluidic pathway, thereby inducing a pH shift configured to release the nucleic acid sample from the set of moiety-bound nucleic acid particles. • Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and

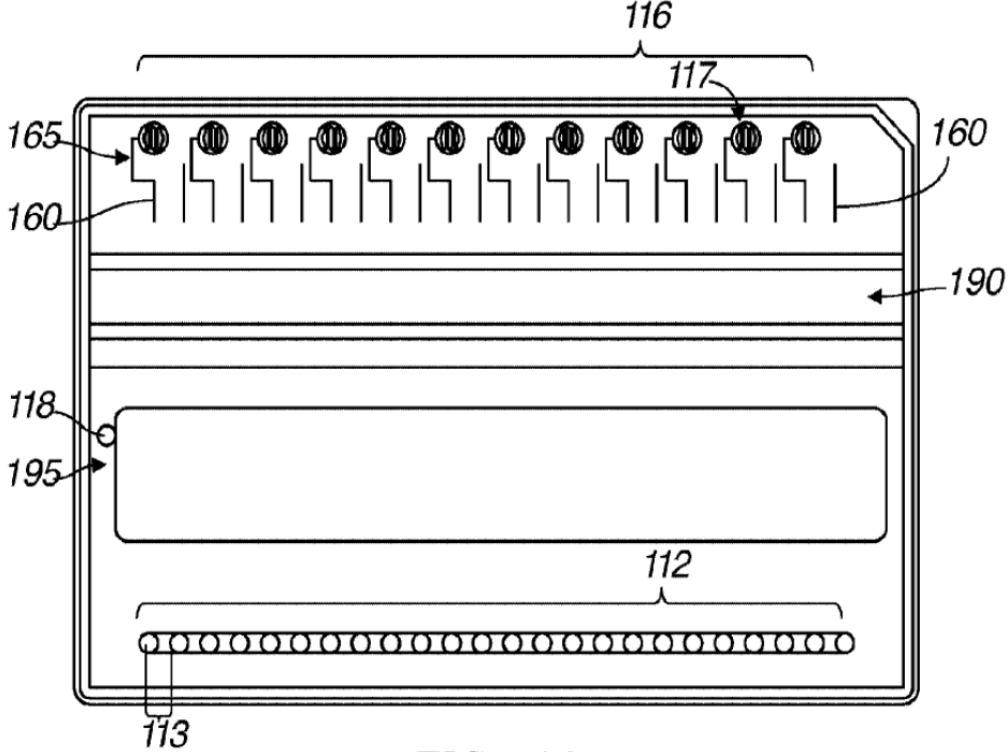
Claim	Claim Language	Infringement Evidence
		<p>RNA from the set of moiety-bound nucleic acid particles, into less than 20uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second subset of the set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction.</p> <ul style="list-style-type: none"> • Claim 18. The method of claim 17, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety-sample mixture from the process chamber; occluding the fluidic pathway of the cartridge at a set of occlusion positions upon displacement of the first subset of the set of pins to generate a path through a magnetic field, and to a waste chamber of the cartridge; and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber. • Claim 19. A method for nucleic acid isolation from a biological sample, comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution includes a set of affinity moiety-coated microparticles, comprising a set of microparticles amide-bonded to at least one of Poly(allylamine) of molecular weight <30,000 Da and Polypropylenimine tetramine dendrimer Generation 1; producing a moiety-sample mixture upon combination of the binding moiety solution with the biological sample; producing a set of moiety-bound nucleic acid particles upon incubation of the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of the set of pins includes reversing displacement of at least one pin of the first subset of the set of pins, and reversing occlusion of a portion of the fluidic pathway. • U.S. Patent No. 9,382,532 at 7:14-53 (“In Step S140, the lysed moiety-sample solution can be processed within the process chamber to separate the moiety-bound nucleic acid volume from the waste volume; however, the lysed moiety-sample solution can alternatively be transferred to another suitable vessel for separation of the moiety-bound nucleic acid volume from the waste volume. In a first variation, a pipetting system (automatic or manual) can be used to remove the waste volume (e.g., supernatant liquid),

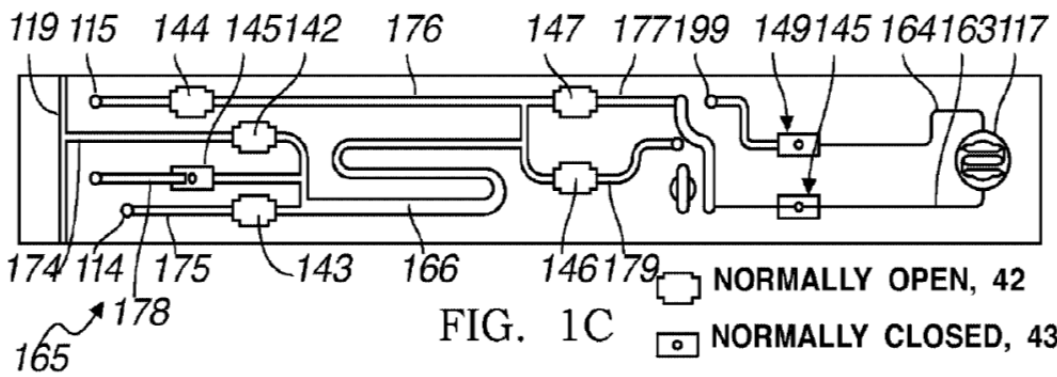
Claim	Claim Language	Infringement Evidence
		<p>and multiple aspirations by the pipetting system may be necessary to ensure as complete a removal of the supernatant as possible. In an example of the first variation, a 1000 micro liter pipette tip can be used to perform gross removal of the waste volume in a first aspiration followed by the use of a finer pipette tip (e.g., 100-200 microliter tip) in additional aspirations, to remove the remainder of the waste volume. In the example, the removal of the waste volume occurs close to the bottom of the process chamber to provide complete liquid removal with minimal bubbling. In a second variation, the lysed moiety-sample solution can be transferred to a vessel that enables the moiety-bound nucleic acid volume to be captured and the waste volume to be removed in a flow through manner, either against the pores of a filter or in the presence of a magnetic field. In the second variation, the microparticles with bound nucleic acids are retained in a filter zone or a magnetic field zone of the vessel, and the liquid portion is flowed into a "waste chamber". In a specific example of the second variation, a system (such as the one described in U.S. patent application Ser. No. 13/766,359, entitled "System and Method for Processing and Detecting Nucleic Acids") can be used to transfer the lysed moiety-sample solution into a fluidic pathway of a cartridge (such as the one described in U.S. patent application Ser. No. 13/765,996, entitled "Microfluidic Cartridge for Processing and Detecting Nucleic Acids"). In the specific example, the lysed moiety-sample solution can be retained by a magnetic field within a portion of the fluidic pathway upon occlusion of the fluidic pathway at a suitable set of occlusion positions, in order to separate the moiety-bound nucleic acid volume from the waste volume. The waste volume can then be removed by pushing the waste volume to a waste chamber of the cartridge.”)</p> <ul style="list-style-type: none"> • Patent No. 9,382,532 at 8:41-55 (“In a variation of the first example of Step S150, a system (such as the one described in U.S. patent application Ser. No. 13/766,359, entitled "System and Method for Processing and Detecting Nucleic Acids") can be used to deliver the wash solution into a fluidic pathway of a cartridge (such as the one described in U.S. patent application Ser. No. 13/765,996, entitled "Microfluidic Cartridge for Processing and Detecting Nucleic Acids"). In the variation of the first example, the microparticles of the moiety-bound nucleic acid volume can be retained by a magnetic field within a portion of the fluidic pathway upon occlusion of the fluidic pathway at a suitable set of occlusion positions, and the wash solution can be delivered through the portion of the fluidic pathway and into a waste chamber of the cartridge to wash the microparticles with the bound target nucleic acid(s).”) • Patent No. 9,382,532 at 23:23-28 (“In a specific example, the valve actuation subsystem 170 comprises 12 sets of pins 172 configured to selectively occlude 12 fluidic pathways 212 of a microfluidic cartridge 210 aligned within the molecular diagnostic module; however, other embodiments may comprise any appropriate number of sets of pins 172.”)

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> Patent No. 9,382,532 at 24:1-12 (“A first illustration of the eighteenth example, as shown in FIG. 22A, of a fluidic pathway 165 preferably comprises an initial segment 174 fluidically coupled to a fluid channel 119 coupled to a shared fluid port 118, a sample segment 175 coupled to a sample port 114 and to the initial segment 174, and an s-shaped capture segment 166, configured to pass through the heating region 195 and a magnetic field 156, coupled to the initial segment 174 and the sample segment 175. In an alternative illustration of the eighteenth example, the s-shaped capture segment 166 may comprise an initial wide arc 166 to provide a greater surface area for magnetic bead capture.”) Patent No. 9,382,532 at 24:53-25:16 (“The occlusion positions of the set of occlusion positions 141 of the first illustration are preferably located such that occluding subsets of the set of occlusion positions 141 defines unique truncated fluidic pathways to controllably direct fluid flow. For example, as shown in FIG. 22B, occluding the fluidic pathway 165 at the first, third, fourth, and sixth occlusion positions 142, 144, 145, 147 forms a truncated pathway by which a volume of a sample fluid, comprising nucleic acids bound to magnetic beads and delivered into the sample port 114, may flow past the second occlusion positions 143 into the capture segment 166 for isolation and purification of nucleic acids using the heating region 195 and the magnetic field 156. Nucleic acids bound to magnetic beads may thus be trapped within the capture segment 166 by the magnetic field 156, while other substances in the volume of sample fluid may pass into the waste chamber 130 by passing the fifth occlusion position 146. Following this subset of occlusion positions, the occlusion at the first occlusion position 142 may be reversed, as shown in FIG. 22C, and the fluidic pathway 165 may be occluded at the second occlusion position 143 to form a second truncated pathway by which a wash fluid may be delivered through the fluid port 118, into the capture segment 166 (thus washing the trapped magnetic beads), and into the waste chamber 130 by passing the fifth occlusion position 146. The occlusion at the second occlusion position 143 may then be reversed, and the first occlusion position 142 may be occluded (as shown in FIG. 22B), so that other fluidic pathways in the set of fluidic pathways 160 may be washed. After all fluidic pathways have been washed, a volume of air may be transferred through the fluid port 118 to prevent mixture of a wash solution with a release solution.”) Patent No. 9,382,532 at 25:30-50 (“Thereafter, the occlusion at the fourth occlusion position 145 maybe reversed, creating a fifth truncated pathway, and release solution within the fluidic pathway 165 may be metered by pumping air through the fluid port 118, which functions to push a portion of the release solution into the waste chamber 130. A volume of release solution will still be maintained within the capture segment 166 at this stage. The first and the fourth occlusion positions 142, 145 may then be occluded to form a sixth truncated pathway sealing the volume of release solution, with the captured

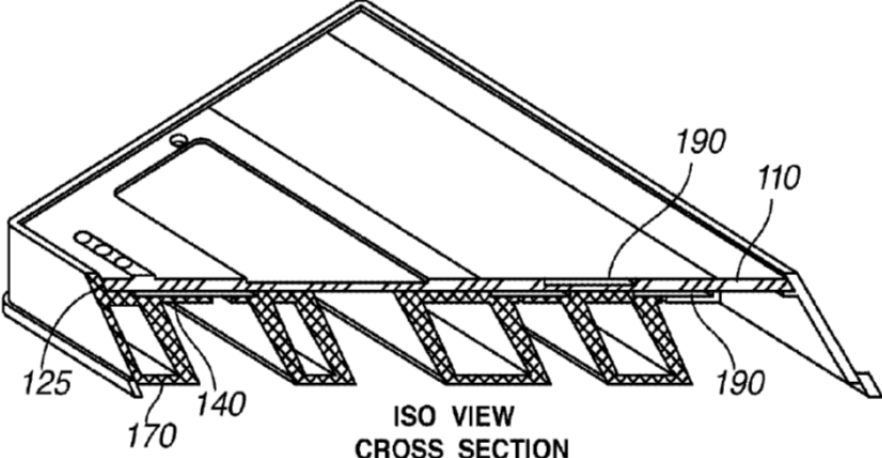
Claim	Claim Language	Infringement Evidence
		<p>magnetic beads bound to nucleic acids, within the capture segment 166. The volume of the remaining release solution is therefore substantially defined by the microchannel volume between junctions in the fluidic pathway 165 near the fourth and sixth occlusion positions 145, 147, and maybe any small volume but in a specific variation is precisely metered to be 23+/-1 microliters. Release solution may be sealed within capture segments of other fluidic pathways using a similar process. A heater may then be provided at the sixth truncated pathway, inducing a pH shift within the sixth truncated pathway to unbind nucleic acids from the magnetic beads.")</p> <ul style="list-style-type: none"> Patent No. 9,382,532 at 26:28-34 ("A second illustration of the eighteenth example, of a fluidic pathway 165' preferably comprises an initial segment 174 fluidically coupled to a fluid channel 119' coupled to a shared fluid port 118', a sample segment 175' coupled to a sample port 114' and to the initial segment 174', and a capture segment 166', configured to pass through the heating region 195 and a magnetic field 156, coupled to the initial segment 174'.") Patent No. 9,382,532 at 27:17-42 ("The occlusion positions of the set of occlusion positions 141' of the second illustration are preferably located such that occluding of subsets of the set of occlusion positions 141' defines unique truncated fluidic pathways to controllably direct fluid flow. For example, occluding the fluidic pathway 165' at the first, fourth, sixth, tenth, and eleventh occlusion positions 142', 145', 147', 158', 159' forms a truncated pathway by which a volume of a sample fluid, comprising nucleic acids bound to magnetic beads and delivered into the sample 25 port 114, may flow into the capture segment 166' for isolation and purification of nucleic acids using the heating region 195 and the magnetic field 156. Nucleic acids bound to magnetic beads may thus be trapped within the capture segment 166' by the magnetic field 156, while other substances in the volume of sample fluid may pass into the waste chamber 130 by passing the fifth occlusion position 146'. Following this subset of occlusion positions, the occlusion at the first occlusion position 142' may be reversed, and the fluidic pathway 165' may be occluded at the second occlusion position 143' to form a second truncated pathway by which a wash fluid may be delivered through the fluid port 118, into the capture segment 166' (thus washing the trapped magnetic beads), and into the waste chamber 130 by passing the fifth occlusion position 146'. A volume of air may then be pumped through the fluid port 118 to flush any remaining wash solution into the waste chamber 130.") <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled to the first

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		<p>layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position of the fluidic pathway, by way of the void of the corrugated surface, the fluidic pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber.</p> <ul style="list-style-type: none"> • Claim 3. The cartridge of claim 1, wherein the waste chamber comprises at least one waste inlet in communication with the opening of the intermediate substrate, and wherein the corrugated surface of the waste chamber further defines a rectangular prismatic void spanning a long dimension of the cartridge that defines a magnet housing region configured to reversibly receive a magnet from the direction perpendicular to a broad face of the first layer, and configured to cross the fluidic pathway. • Claim 4. The cartridge of claim 3, wherein the fluidic pathway comprises a capture segment, downstream of the sample port and configured to cross the magnet housing region multiple times. • U.S. Patent No. 9,403,165 at 2:39-3:6 (“As shown in FIGS. 1A-1C, an embodiment of a microfluidic cartridge 100 for processing and detecting nucleic acids comprises: a top layer 110 comprising a set of sample port-reagent port pairs 112 and a set of detection chambers 116; an intermediate substrate 120, coupled to the top layer 110 and partially separated from the top layer by a film layer 125, configured to form a waste chamber 130; an elastomeric layer 140 partially situated on the intermediate substrate 120; a magnet housing region 150 accessible by a magnet 152 providing a magnetic field 156; and a set of fluidic pathways 160, each formed by at least a portion of the top layer 110, a portion of the film layer 125, and a portion of the elastomeric layer 140. In other embodiments, the microfluidic cartridge 100 may further comprise a bottom layer 170 coupled to the intermediate substrate 120 and configured to seal the waste chamber 130. Furthermore, the top layer 110 of the microfluidic cartridge 100 may further comprise a shared fluid port 118, a vent region 190, and a heating region 195, such that each fluidic pathway 165 in the set of fluidic pathways 160 is fluidically coupled to a sample port-reagent port pair 113, the shared fluid port 118, the waste chamber 130, and a detection chamber 117, comprises a capture segment 166 configured to pass through the heating region and the magnetic field, and is configured to pass through the vent region 190 upstream of the detection chamber 117. Each fluidic pathway 165 thus functions to receive and facilitate processing of a sample fluid containing nucleic acids as it passes through different portions of the fluidic pathway 165. As configured, the microfluidic

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		<p>cartridge 100 can be used to facilitate molecular diagnostic processes and techniques, and preferably conforms to microtiter plate dimensional standards. Alternatively, the microfluidic cartridge 100 may be any appropriate size. In a specific application, the microfluidic cartridge 100 can be used to facilitate a PCR procedure for analysis of a sample containing nucleic acids.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at FIG. 1A.  <p style="text-align: center;">FIG. 1A</p> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at FIG. 1C.

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		 <p>FIG. 1C</p> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at 7:66-8:22. (“The top layer 110 of the microfluidic cartridge 100 may further comprise a set of cartridge-aligning indentations 180, which function to align the microfluidic cartridge 100 as it moves through an external module. As shown in FIG. 2 the set of cartridge-aligning indentations 180 are preferably located such that they do not interfere with any ports 112, 118, the heating region, 195, the vent region 190, and/or the set of detection chambers 116. In an embodiment, the top layer 110 of the microfluidic cartridge preferably comprises at least four cartridge-aligning indentations, located at points on the periphery of the top layer 110, and the cartridge-aligning indentations are configured to be recessed regions configured to mate with alignment pins in a system external to the microfluidic cartridge 100. Alternatively, the cartridge-aligning indentations may be grooves, such that the microfluidic cartridge 100 accurately slides into position along the grooves within a system external to the microfluidic cartridge 100. In yet another alternative embodiment, the set of cartridge-aligning indentations 180 may be any appropriate indentations that allow for positioning of the microfluidic cartridge 100 within an external system. However, the microfluidic cartridge 100 may altogether omit the set of cartridge-aligning indentations 180, and rely upon other features of the microfluidic cartridge 100 to facilitate alignment.”) U.S. Patent No. 9,403,165 at 12:59-13:21 (“Preferably, the magnet housing region 150 is bounded on at least two sides by the waste chamber 130, and positioned near the middle of the microfluidic cartridge 100, such that a fluidic pathway 165 passing through the magnetic field 156 passes through the magnetic field 156 at least at one point along an intermediate portion of the fluidic pathway 165. Preferably, the magnet housing region 150 also substantially spans at least one dimension of the microfluidic cartridge, such that multiple fluidic pathways 165 of the microfluidic cartridge 100

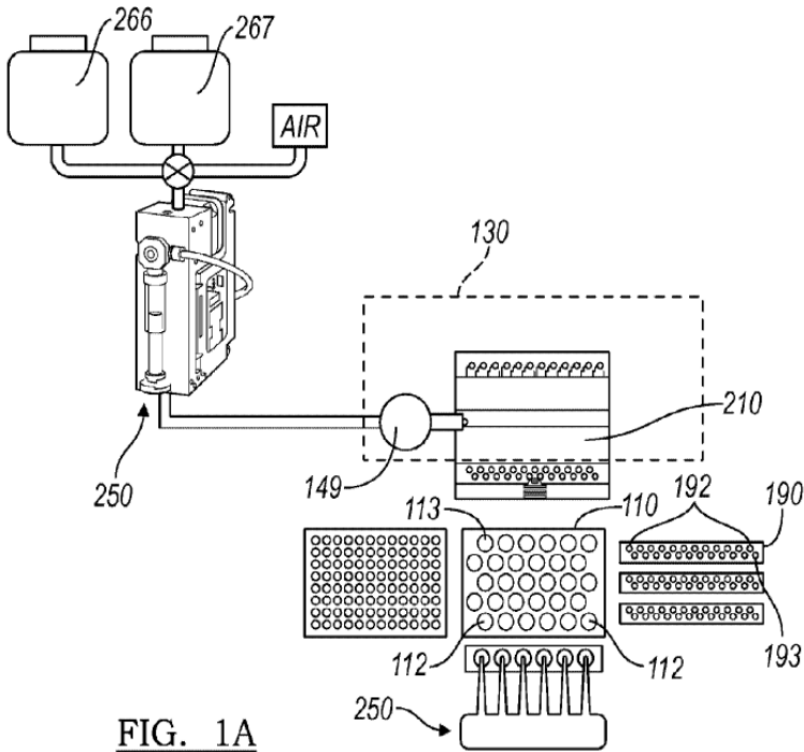
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		<p>cross the same magnet housing region 150, magnet 152, and/or magnetic field 156. Alternatively, the magnet housing region 150 may be configured such that a magnet within the magnet housing region 150 provides a magnetic field spanning all fluidic pathways 165 of the microfluidic cartridge in their entirety. In alternative embodiments, the microfluidic cartridge may comprise more than one magnet housing region 150, a magnet housing region 150 may be configured to receive and/or house more than one magnet 152, and/or may not be positioned near the middle of the microfluidic cartridge 100. In yet another alternative embodiment, the magnet housing region 150 may permanently house a magnet 152, such that microfluidic cartridge comprises a magnet 152, integrated with the intermediate substrate 120. In embodiments where the magnet 152 is retractable from the microfluidic cartridge 100, the magnet 152 may be a permanent magnet or an electromagnet. In embodiments where the magnet 152 is configured to be integrated with the microfluidic cartridge 100, the magnet 152 is preferably a permanent magnet, which provides a stronger magnetic field per unit volume.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,403,165 at 13:40-51 (“Furthermore, at least one fluidic pathway 165 in the set of fluidic pathways 160 is preferably configured to be occluded upon deformation of the elastomeric layer 140, configured to transfer a waste fluid to the waste chamber 30, comprises a capture segment 166 passing through the heating region 195 and a magnetic field 156, and is configured to pass through the vent region 190 upstream of a detection chamber 117. Alternative embodiments may omit preferred elements of the embodiment of the fluidic pathway 165 described above, such as a vent region 190 or a heating region 195, or add additional elements to the embodiment of the fluidic pathway 165 described above.”) • U.S. Patent No. 9,403,165 at 14:39-56 (“As shown in FIGS. 1C, 6C, 7 and 9, a fluidic pathway 165 of the set of fluidic pathways 160 is branched and preferably comprises an initial segment 174 fluidically coupled to a fluid channel 119 coupled to a fluid port 118, a sample segment 175 coupled to a sample port 114, a reagent segment 176 coupled to a reagent port 115, a capture segment 166 passing through at least one of the heating region 195 and a magnetic field 156, a vent segment 177 configured to pass through the vent region 190, a segment running to a detection chamber 163, a segment running away from the detection chamber 164, and at least one waste segment 178, 179 configured to transfer a waste fluid to a waste chamber 130. Individual segments of the fluidic pathway 165 are preferably configured to pass through at least one occlusion position of the set of occlusion positions 141, to controllably direct fluid flow through portions of the fluidic pathway 165. A fluidic pathway 165 may also further comprise an end vent 199, which functions to prevent any fluid from escaping the microfluidic channel.”) • U.S. Patent No. 9,403,165 at 10:35-42 (“In an embodiment of the waste chamber 130 with a corrugated

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		<p>surface 137, at least two ridges of the corrugated surface 137 are preferably the same height, such that the microfluidic cartridge 100 sits substantially level on a flat base. In an alternative embodiment, all ridges of the corrugated surface 137 of the waste chamber 130 are identical, for structural symmetry, and in yet another embodiment, the waste chamber 130 may not have a corrugated surface 137.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at FIG. 4.  <p style="text-align: center;">FIG. 4</p> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at 15:22-51 (“A first embodiment, as shown in FIG. 1C, of a fluidic pathway 165 preferably comprises an initial segment 174 fluidically coupled to a fluid channel 119 coupled to a shared fluid port 118, a sample segment 175 coupled to a sample port 114 and to the initial segment 174, and an s-shaped capture segment 166, configured to pass through the heating region 195 and a magnetic field 156, coupled to the initial segment 174 and the sample segment 175. In a variation of the first embodiment, the s-shaped capture segment 166 may comprise an initial wide arc 166 to provide a greater surface area for magnetic bead capture. In another variation of the first embodiment, the capture segment 166 may alternatively be a progressively narrowing s-shaped capture segment 166. The first embodiment of the fluidic pathway 165 also comprises a reagent segment 176 coupled to a reagent port 115 and to the capture segment 166, a vent segment 177 coupled to the reagent segment 176 and configured to pass through the vent region 190, a segment running to a detection chamber 163 from the vent region 190, a winding segment running away from the detection chamber 164, and an end vent 199

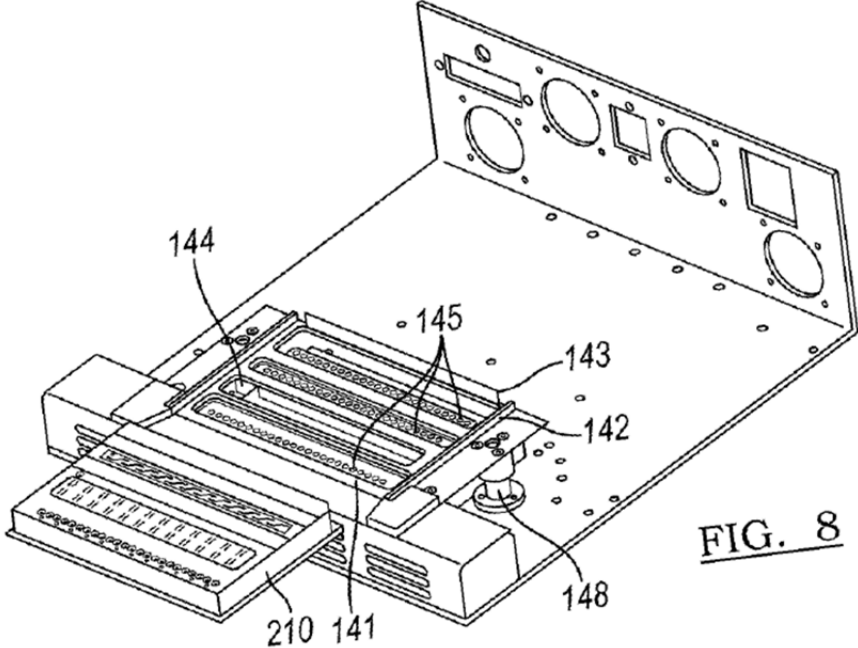
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		<p>coupled to the segment running away from the detection chamber 164. The first embodiment of the fluidic pathway 165 also comprises a first waste segment 178 configured to couple the initial segment 174 to the waste chamber 130, and a second waste segment 179 configured to couple the capture segment 166 to the waste chamber 130. The first waste segment 178 preferably functions to allow evacuation of excess release fluids from a fluidic pathway 165, for precise metering of the amount of release reagents used in a molecular diagnostic procedure using a low volume of sample.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,403,165 at 16:7-23 (“The occlusion positions of the set of occlusion positions 141 of the first embodiment are preferably located such that occluding subsets of the set of occlusion positions 141 defines unique truncated fluidic pathways to controllably direct fluid flow. For example, as shown in FIG. 1D, occluding the fluidic pathway 165 at the first, third, fourth, and sixth occlusion positions 142, 144, 145, 147 forms a truncated pathway by which a volume of a sample fluid, comprising nucleic acids bound to magnetic beads and delivered into the sample port 114, may flow past the second occlusion positions 143 into the capture segment 166 for isolation and purification of nucleic acids using the heating region 195 and the magnetic field 156. Nucleic acids bound to magnetic beads may thus be trapped within the capture segment 166 by the magnetic field 156, while other substances in the volume of sample fluid may pass into the waste chamber 130 by passing the fifth occlusion position 146.”) • U.S. Patent No. 9,403,165 16:58-17:5 (“As shown in FIG. 1H, the first and the fourth occlusion positions 142, 145 may then be occluded to form a sixth truncated pathway sealing the volume of release solution, with the captured magnetic beads bound to nucleic acids, within the capture segment 166. The volume of the remaining release solution is therefore substantially defined by the microchannel volume between junctions in the fluidic pathway 165 near the fourth and sixth occlusion positions 145, 147, and may be any small volume but in a specific variation is precisely metered to be 23+/-1 microliters. Release solution may be sealed within capture segments of other fluidic pathways using a similar process. A heater may then be provided at the sixth truncated pathway, inducing a pH shift within the sixth truncated pathway to unbind nucleic acids from the magnetic beads.”) • U.S. Patent No. 9,403,165 at 18:40-65 (“The occlusion positions of the set of occlusion positions 141’ of the second embodiment are preferably located such that occluding of subsets of the set of occlusion positions 141’ defines unique truncated fluidic pathways to controllably direct fluid flow. For example, occluding the fluidic pathway 165’ at the first, fourth, sixth, tenth, and eleventh occlusion positions 142’, 145’, 147’, 158’, 159’ forms a truncated pathway by which a volume of a sample fluid, comprising nucleic acids bound to magnetic beads and delivered into the sample port 114, may flow into the capture segment 166’ for isolation and purification of nucleic acids using the heating region 195 and

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		<p>the magnetic field 156. Nucleic acids bound to magnetic beads may thus be trapped within the capture segment 166' by the magnetic field 156, while other substances in the volume of sample fluid may pass into the waste chamber 130 by passing the fifth occlusion position 146'. Following this subset of occlusion positions, the occlusion at the first occlusion position 142' may be reversed, and the fluidic pathway 165' may be occluded at the second occlusion position 143' to form a second truncated pathway by which a wash fluid may be delivered through the fluid port 118, into the capture segment 166' (thus washing the trapped magnetic beads), and into the waste chamber 130 by passing the fifth occlusion position 146'. A volume of air may then be pumped through the fluid port 118 to flush any remaining wash solution into the waste chamber 130.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at 24:39-49 (“The fluidic pathways 165 of the specific embodiment are, in their default condition, open at all occlusion positions, aside from the fourth, seventh, and eighth, occlusion positions 145, 148, 149, as shown in FIG. 1C. Furthermore, the s-shaped capture segment 166 of a fluidic pathway of the specific embodiment is configured to have a volume capacity of 22 ~LL, have a width of 5 .5 mm, and weave back and forth over a magnetic field 156, by crossing the magnet housing region 150. The depth of the s-shaped capture segment 166 is 0.4 mm for the 1.6 mm wide channels and 0.475 for the 0.5 mm narrower channel.”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. Claim 8. The system of claim 1, wherein the magnet is configured to provide a magnetic field spanning at least three fluidic pathways configured to facilitate isolation and extraction of three

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		<p>nucleic acid volumes.</p> <ul style="list-style-type: none"> • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) • U.S. Patent No. 9,050,594 at 2:49-58 (“As shown in FIGS. 1A-1B and 7A, an embodiment of a system

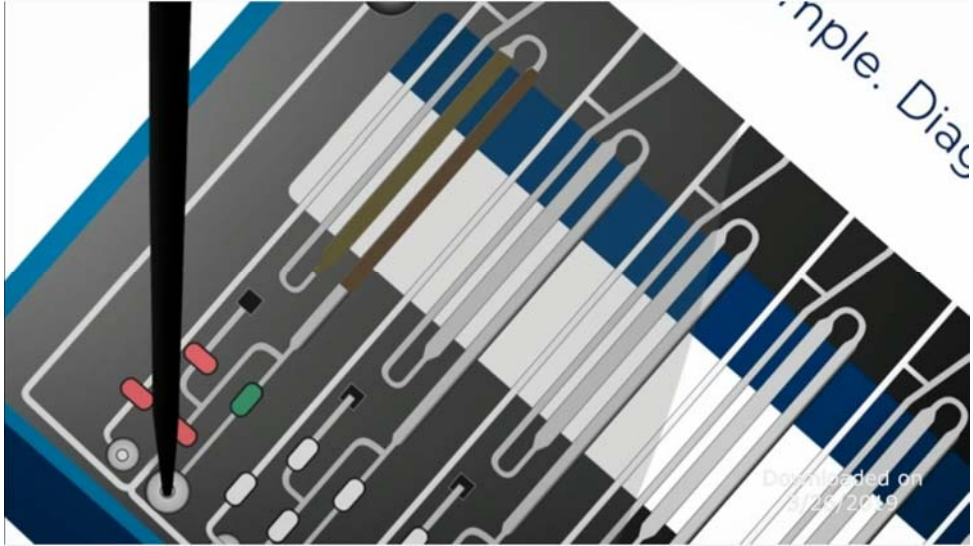
Claim	Claim Language	Infringement Evidence
		<p>100 for processing and detecting nucleic acids comprises: a capture plate 110 configured to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119; a molecular diagnostic module 130 comprising a microfluidic cartridge receiving module 140, heating and cooling subsystem 150, a magnet 160, a valve actuation subsystem 170, an optical subsystem 180; and an assay strip 190 configured to facilitate mixing of molecular diagnostic reagents with a nucleic acid volume.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at FIG. 1A.  <p style="text-align: center;">FIG. 1A</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 7:53-8:6 (“As shown in FIG. 9A, the cartridge receiving module 140 of

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		<p>the molecular diagnostic module 130 comprises a cartridge platform 141 including a cartridge loading guiderail 142, a cartridge stop 143, a magnet receiving slot 144, and a set of valve actuation slots 145; a linear actuator 146 configured to displace a microfluidic cartridge 210 resting on the cartridge platform 141, and a set of springs 148 coupled to the cartridge platform 141. The cartridge receiving module 140 thus functions to receive, align, and compress a microfluidic cartridge 210 for processing of a biological sample according to a molecular diagnostic assay protocol. As shown in FIGS. 7A-7C, the cartridge platform 141 is preferably configured to receive a microfluidic cartridge 210 along a cartridge loading guiderail 142 until it reaches a cartridge stop 143, and be vertically displaced by the linear actuator 146, which places a biasing force against the set of springs 148 coupled to the cartridge platform 141. The magnet receiving slot 144 and the set of valve actuation slots 145 provide access, by a magnet 160 and a valve actuation subsystem 170, to the microfluidic cartridge 210, as the microfluidic cartridge is vertically displaced by the linear actuator 146.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 7A. <div data-bbox="709 711 1564 1182"> <p style="text-align: center;">FIG. 7A</p> </div> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 8:7-35 (“The cartridge platform 141 includes a cartridge loading guiderail 142, a cartridge stop 143, a magnet receiving slot 144, and a set of valve actuation slots 145, and functions to receive and align a microfluidic cartridge 210, while providing access to the microfluidic cartridge 210 by a magnet 160 and a valve actuation subsystem 170. As shown in FIG. 8, an embodiment of the cartridge platform 141 includes a pair of parallel cartridge loading guiderails 142, initiating at a pair of inwardly tapering protrusions configured to guide a microfluidic cartridge toward

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		<p>the pair of parallel cartridge loading guiderails 142, and spanning two short edges of the cartridge platform 141. The embodiment of the cartridge platform 141 also includes a cartridge stop 143 comprising a vertical tab oriented perpendicular to the cartridge loading guiderails 142, and spanning a long edge of the cartridge platform. Preferably, the cartridge loading guiderails 142 and the cartridge stop 143 are configured such that a microfluidic cartridge 210 slides between the cartridge loading guiderails 142 and hits the cartridge stop 143 to signal proper alignment. Alternatively, the cartridge loading guiderails 142 and the cartridge stop 143 may be configured such that a microfluidic cartridge slides over or along the cartridge loading guiderails 142, after which the cartridge stop 143 couples to a portion of the microfluidic cartridge 210 to ensure proper alignment of the microfluidic cartridge. Additional variations of the cartridge loading guiderails 142 and the cartridge stop 143 may be used to enable reception and alignment of a microfluidic cartridge 210 by the molecular diagnostic module 130, and are known by those skilled in the art.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at FIG. 8.  <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 10:5-26 (“Similarly, the nozzle 149, the heating and cooling subsystem 150,

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		<p>the cartridge heater 153, and the magnet 160 are preferably coupled to springs, such that springs are positioned between elements 149,150, 153, and 160, and substrates that elements 149, 150, 153, and 160 are mounted to. Alternatively an elastomeric material is preferably positioned between elements 149,150, 153, and 160, and substrates that elements 149, 150, 153, and 160 are mounted to. The springs and/or elastomeric material function to provide proper functioning and alignment of subsystems of the molecular diagnostic module 130 as the linear actuator 146 is extended or retracted, contributing to reliability and a reduction in stack up tolerance risk. The springs and/or elastomeric material further function to allow more pressure to be applied to occlusion positions of a microfluidic cartridge 210 aligned within the molecular diagnostic module 130, and an appropriate pressure to be applied to elements 149, 150, 153 and 160 of the molecular diagnostic module 130. Thus, proper contact is maintained between elements 149, 150, 153, and 160, and a microfluidic cartridge 210 being manipulated by the molecular diagnostic module. These elements are described in further detail below.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 10:29-44 (“The heating and cooling subsystem 150 of the molecular diagnostic module 130 comprises a cartridge heater 153, a fan 155, and a set of detection chamber heaters 157 and functions to controllably heat portions of a microfluidic cartridge 210 for processing of a biological sample containing nucleic acids according to a molecular diagnostic protocol. In the orientation of an embodiment of the molecular diagnostic module 130 shown in FIGS. 7A-7C, the cartridge heater 153 is preferably coupled to the linear actuator 146 of the cartridge receiving module 140 and configured to span a central region of a microfluidic cartridge 210 aligned within the molecular diagnostic module 130, the fan 155 is located at a back wall of the cartridge receiving module 140, and the set of detection chamber heaters 157 is located inferior to a set of detection chambers 213 of the microfluidic cartridge 210. In alternative embodiments of the molecular diagnostic module 130, the heating and cooling subsystem 150 may have any appropriate alternative configuration that provides controlled heating and cooling to a microfluidic cartridge within the molecular diagnostic module 130.”) • U.S. Patent No. 9,050,594 at 22:61-23:20 (“The microfluidic cartridge 210 is preferably configured to be received and manipulated by the molecular diagnostic module 130, such that the cartridge receiving module 140 of the molecular diagnostic module 130 receives and aligns the microfluidic cartridge 210 within the molecular diagnostic module 130, the heating and cooling subsystem 150 of the molecular diagnostic module 130 is configured to transfer heat to the heating region 224 of the microfluidic cartridge 210, and the magnet 160 of the molecular diagnostic module 130 is configured to be received by the magnet housing region 218 of the microfluidic cartridge 210 to provide a magnetic field for separation of nucleic acids. The elastomeric layer 217 of the microfluidic cartridge 210 is also

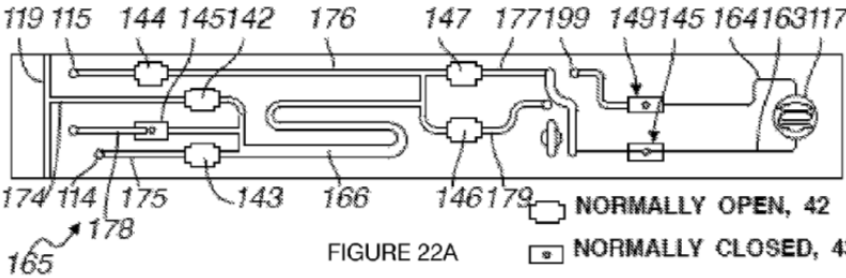
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		<p>preferably configured to be occluded at a set of occlusion positions 226 by the valve actuation subsystem 170 of the molecular diagnostic module, in order to occlude portions of a fluidic pathway 220 of the microfluidic cartridge 210 for processing of a set of biological samples. The optical subsystem 180 of the molecular diagnostic module 130 is further configured to align with the set of detection chambers 213 of the microfluidic cartridge 210, to facilitate analysis of a set of nucleic acid samples.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 28:53-29:4 (“Step S430 recites transferring each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways, and functions to isolate each of the set of nucleic acid-magnetic bead samples within separate pathways for further processing. Preferably, all nucleic acid-magnetic bead samples in the set of nucleic acid-magnetic bead samples are transferred simultaneously to the set of fluidic pathways, but alternatively, each nucleic acid-magnetic bead sample in the set of magnetic bead-samples may be transferred to a corresponding fluidic pathway independently of the other nucleic acid-magnetic bead samples. In addition, preferably the entire volume, or substantially all of the volume, of the nucleic acid-magnetic bead sample is transferred to the set of fluidic pathways, without magnetically isolating magnetic beads and removing supernatant fluids prior to transferring each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways.”) • U.S. Patent No. 9,050,594 at 29:5-11 (“Step S430 may further comprise occluding at least one fluidic pathway of the set of fluidic pathways at a subset of a set of occlusion positions S432, which functions to define at least one truncated fluidic pathway. Preferably, Step S432 comprises defining at least one truncated fluidic pathway passing through at least one of a heating region and a magnetic field;”) • U.S. Patent No. 9,050,594 at 29:14-26 (“In a specific example of Step S430, the multichannel liquid handling subsystem of Step S410 transfers a set of nucleic acid-magnetic bead samples to a set of fluidic pathways of a microfluidic cartridge aligned within a molecular diagnostic module, wherein the microfluidic cartridge comprises an elastomeric layer in contact with the set of fluidic pathways. Manipulation of the elastomeric layer at a subset of a set of occlusion positions by a valve actuation subsystem of the molecular diagnostic module defines a set of truncated fluidic pathways crossing a heating region and a magnetic field, such that each nucleic acid-magnetic bead sample in the set of nucleic acid-magnetic bead samples is isolated within a truncated fluidic pathway of the set of truncated fluidic pathways.”)
1(e)	a waste chamber in the	In the accused system, the first module comprises, a waste chamber in the first module, the waste chamber

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	first module, the waste chamber corresponding to a process chamber of the plurality of process chambers in the first module,	<p>corresponding to a process chamber of the plurality of process chambers in the first module.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” <i>Id.</i> at 2:28-2:39. • <i>Id.</i> at 2:28 (showing excess solution (light brown) flowing into a self-contained waste chamber).  <ul style="list-style-type: none"> • “A precise volume of air is then applied to remove any remaining liquid into the waste chamber. NeuMoDx wash solution is pumped via the fluid port into the microfluidic cartridge to remove all unbound material, followed by another volume of air to remove excess wash solution. High pH NeuMoDx release reagent is dispensed into the s-channel to cover the beads, and heat is applied to the denaturation process, resulting in released nucleic acid or eluate.” <i>Id.</i> at 2:39-3:12. <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY (Exhibit 19)</p> <ul style="list-style-type: none"> • “Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent

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		<p>processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System. The NeuMoDx Cartridge also incorporates a chamber to contain all the liquid waste generated in the course of processing the samples.” <i>Id.</i> at 1.</p> <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> • Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10. • Claim 5. The method of claim 3, wherein separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture. • Claim 6. The method of claim 5, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety-sample mixture from the process chamber; occluding the fluidic pathway of the cartridge-at a set of occlusion positions upon displacement of pins of the set of pins to generate a path through a magnetic field, and to a waste chamber; and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber.

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • Claim 10. The method of claim 3, wherein washing the set of moiety-bound nucleic acid particles comprises aspirating the moiety-sample mixture; receiving the cartridge at the cartridge receiving module comprising the set of pins and a cam card interfacing with the set of pins; transitioning the cartridge to an active configuration that disposes the cartridge proximal the set of pins; displacing the first subset of the set of pins in the active configuration of the cartridge, upon translation of the cam card relative to the set of pins, thereby occluding the fluidic pathway of the cartridge at a set of occlusion positions; delivering the moiety-sample mixture into the fluidic pathway, wherein the fluidic pathway is configured to pass through a magnetic field and is coupled to a waste chamber, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field; and delivering a wash solution through the fluidic pathway and into the waste chamber in a continuous flow operation. • Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second subset of the set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction. • Claim 18. The method of claim 17, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety-sample mixture from the process chamber; occluding the fluidic pathway of the cartridge at a set of occlusion positions upon displacement of the first subset of the set of pins to generate a path through a magnetic field, and to a waste chamber of the cartridge; and delivering the moiety-sample mixture through the path of the fluidic

Claim	Claim Language	Infringement Evidence
		<p>pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber.</p> <ul style="list-style-type: none"> <p>Patent No. 9,382,532 at 6:41-67 (“Step S140 recites separating the moiety-bound nucleic acid volume from the waste volume, and functions to compact or concentrate microparticles coupled to the target nucleic acid(s), by way of the affinity moieties, in order to facilitate removal of the waste volume from the moiety-bound nucleic acid volume. Preferably, the moiety-bound nucleic acid volume is separated using a magnetic-separation method; however the moiety-bound nucleic acid volume can alternatively be separated using methods based upon microparticle size, mass, and/or density (e.g., centrifugation, sedimenting, filtering), and/or focusing methods (e.g., electric field focusing, laser based focusing). Separation in Step S140 can, however, be performed using any other suitable method. In a first variation, wherein the microparticles coupled with affinity moieties have magnetic properties, a magnetic field can be applied to retain the nucleic acid-bound microparticles of the moiety-bound nucleic acid volume, while the waste volume (e.g., cellular debris and other unbound material) is substantially removed by aspiration. In a second variation, wherein the microparticles coupled with affinity moieties have a characteristic dimension for size-based separation, the lysed moiety-sample solution can be filtered to substantially remove the waste volume. In the second variation, the filter is preferably configured to pass the microparticles bound to the target nucleic acids while retaining the waste; however, the filter can alternatively be configured to retain the microparticles while passing the waste.”)</p> <p>U.S. Patent No. 9,382,532 at 7:14-53 “In Step S140, the lysed moiety-sample solution can be processed within the process chamber to separate the moiety-bound nucleic acid volume from the waste volume; however, the lysed moiety-sample solution can alternatively be transferred to another suitable vessel for separation of the moiety-bound nucleic acid volume from the waste volume. In a first variation, a pipetting system (automatic or manual) can be used to remove the waste volume (e.g., supernatant liquid), and multiple aspirations by the pipetting system may be necessary to ensure as complete a removal of the supernatant as possible. In an example of the first variation, a 1000 micro liter pipette tip can be used to perform gross removal of the waste volume in a first aspiration followed by the use of a finer pipette tip (e.g., 100-200 microliter tip) in additional aspirations, to remove the remainder of the waste volume. In the example, the removal of the waste volume occurs close to the bottom of the process chamber to provide complete liquid removal with minimal bubbling. In a second variation, the lysed moiety-sample solution can be transferred to a vessel that enables the moiety-bound nucleic acid volume to be captured and the waste volume to be removed in a flow through manner, either against the pores of a filter or in the presence of a magnetic field. In the second</p>

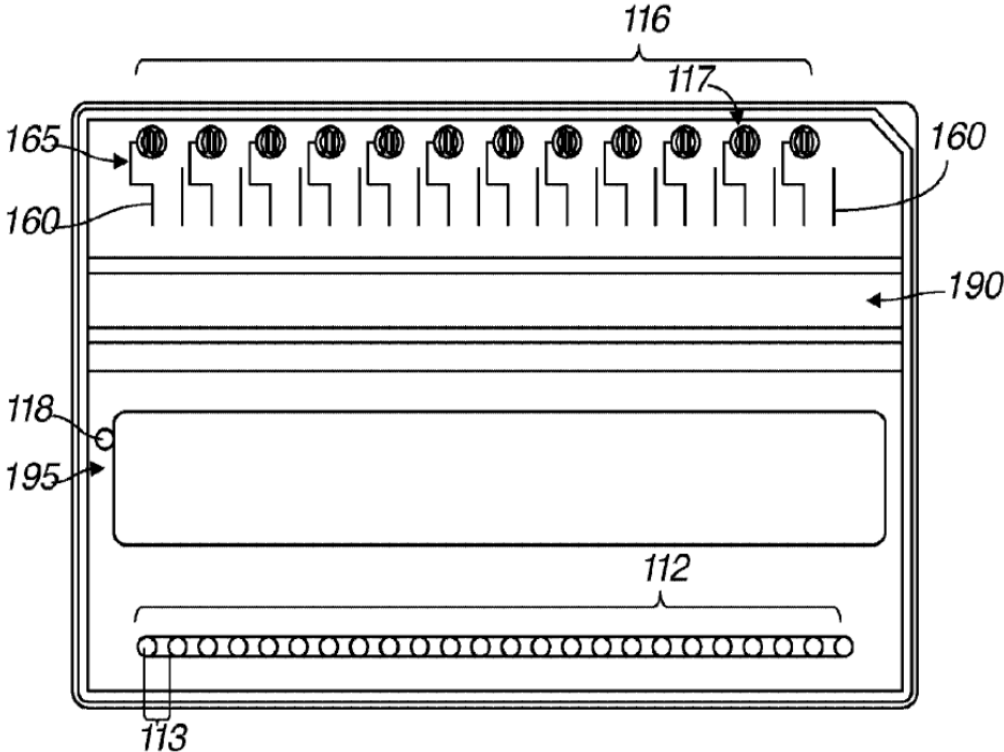
Claim	Claim Language	Infringement Evidence
		<p>variation, the microparticles with bound nucleic acids are retained in a filter zone or a magnetic field zone of the vessel, and the liquid portion is flowed into a "waste chamber". In a specific example of the second variation, a system (such as the one described in U.S. patent application Ser. No. 13/766,359, entitled "System and Method for Processing and Detecting Nucleic Acids") can be used to transfer the lysed moiety-sample solution into a fluidic pathway of a cartridge (such as the one described in U.S. patent application Ser. No. 13/765,996, entitled "Microfluidic Cartridge for Processing and Detecting Nucleic Acids"). In the specific example, the lysed moiety-sample solution can be retained by a magnetic field within a portion of the fluidic pathway upon occlusion of the fluidic pathway at a suitable set of occlusion positions, in order to separate the moiety-bound nucleic acid volume from the waste volume. The waste volume can then be removed by pushing the waste volume to a waste chamber of the cartridge.")</p> <ul style="list-style-type: none"> U.S. Patent No. 9,382,532 at 24:23-31 ("The first illustration of the fluidic pathway 165 also comprises a first waste segment 178 configured to couple the initial segment 174 to the waste chamber 130, and a second waste segment 179 configured to couple the capture segment 166 to the waste chamber 130. The first waste segment 178 preferably functions to allow evacuation of excess release fluids from a fluidic pathway 165, for precise metering of the amount of release reagents used in a molecular diagnostic procedure using a low volume of sample.") U.S. Patent No. 9,382,532 at FIG. 22A:  <p>FIGURE 22A</p> <ul style="list-style-type: none"> Patent No. 9,382,532 at 24:53-25:16 ("The occlusion positions of the set of occlusion positions 141 of the first illustration are preferably located such that occluding subsets of the set of occlusion positions 141 defines unique truncated fluidic pathways to controllably direct fluid flow. For example, as shown in FIG. 22B, occluding the fluidic pathway 165 at the first, third, fourth, and sixth occlusion positions 142, 144, 145, 147 forms a truncated pathway by which a volume of a sample fluid, comprising nucleic acids bound

Claim	Claim Language	Infringement Evidence
		<p>to magnetic beads and delivered into the sample port 114, may flow past the second occlusion positions 143 into the capture segment 166 for isolation and purification of nucleic acids using the heating region 195 and the magnetic field 156. Nucleic acids bound to magnetic beads may thus be trapped within the capture segment 166 by the magnetic field 156, while other substances in the volume of sample fluid may pass into the waste chamber 130 by passing the fifth occlusion position 146. Following this subset of occlusion positions, the occlusion at the first occlusion position 142 may be reversed, as shown in FIG. 22C, and the fluidic pathway 165 may be occluded at the second occlusion position 143 to form a second truncated pathway by which a wash fluid may be delivered through the fluid port 118, into the capture segment 166 (thus washing the trapped magnetic beads), and into the waste chamber 130 by passing the fifth occlusion position 146. The occlusion at the second occlusion position 143 may then be reversed, and the first occlusion position 142 may be occluded (as shown in FIG. 22B), so that other fluidic pathways in the set of fluidic pathways 160 may be washed. After all fluidic pathways have been washed, a volume of air may be transferred through the fluid port 118 to prevent mixture of a wash solution with a release solution.”)</p> <ul style="list-style-type: none"> Patent No. 9,382,532 at 27:17-42 (“The occlusion positions of the set of occlusion positions 141' of the second illustration are preferably located such that occluding of subsets of the set of occlusion positions 141' defines unique truncated fluidic pathways to controllably direct fluid flow. For example, occluding the fluidic pathway 165' at the first, fourth, sixth, tenth, and eleventh occlusion positions 142', 145', 147', 158', 159' forms a truncated pathway by which a volume of a sample fluid, comprising nucleic acids bound to magnetic beads and delivered into the sample 25 port 114, may flow into the capture segment 166' for isolation and purification of nucleic acids using the heating region 195 and the magnetic field 156. Nucleic acids bound to magnetic beads may thus be trapped within the capture segment 166' by the magnetic field 156, while other substances in the volume of sample fluid may pass into the waste chamber 130 by passing the fifth occlusion position 146'. Following this subset of occlusion positions, the occlusion at the first occlusion position 142' may be reversed, and the fluidic pathway 165' may be occluded at the second occlusion position 143' to form a second truncated pathway by which a wash fluid may be delivered through the fluid port 118, into the capture segment 166' (thus washing the trapped magnetic beads), and into the waste chamber 130 by passing the fifth occlusion position 146'. A volume of air may then be pumped through the fluid port 118 to flush any remaining wash solution into the waste chamber 130.”) <p>US9403165 (Exhibit 27)</p>

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position of the fluidic pathway, by way of the void of the corrugated surface, the fluidic pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber. • Claim 3. The cartridge of claim 1, wherein the waste chamber comprises at least one waste inlet in communication with the opening of the intermediate substrate, and wherein the corrugated surface of the waste chamber further defines a rectangular prismatic void spanning a long dimension of the cartridge that defines a magnet housing region configured to reversibly receive a magnet from the direction perpendicular to a broad face of the first layer, and configured to cross the fluidic pathway. • Claim 5. The cartridge of claim 4, wherein the fluidic pathway is configured to transfer waste fluid of the sample to the waste chamber through a first waste inlet upstream of the capture segment by way of a first waste segment fluidly coupled to the first waste inlet and an initiating portion of the capture segment, and wherein the fluidic pathway is configured to transfer a second waste fluid to the waste chamber through a second waste inlet downstream of the capture segment by way of a second waste segment fluidly coupled to the second waste inlet and a terminating portion of the capture segment. • Claim 6. The cartridge of claim 1, wherein the elastomeric layer is situated between the fluidic pathway and the intermediate substrate, wherein the intermediate substrate provides access to a set of occlusion positions of the fluidic pathway through at least at a subset of a set of voids of the corrugated surface of the waste chamber, such that the fluidic pathway is configured to be occluded through the elastomeric layer at the set of occlusion positions from a direction perpendicular to the broad surface of the first layer. • Claim 7. The cartridge of claim 6, wherein at least one void of the set of voids defined by the corrugated surface of the waste chamber is defined by five surfaces of the corrugated surface, including a first pair of parallel surfaces and a second pair of parallel surfaces orthogonal to the first pair of parallel surfaces and orthogonal to the broad surface of the first layer, and a surface, coupled to the first pair of surfaces and

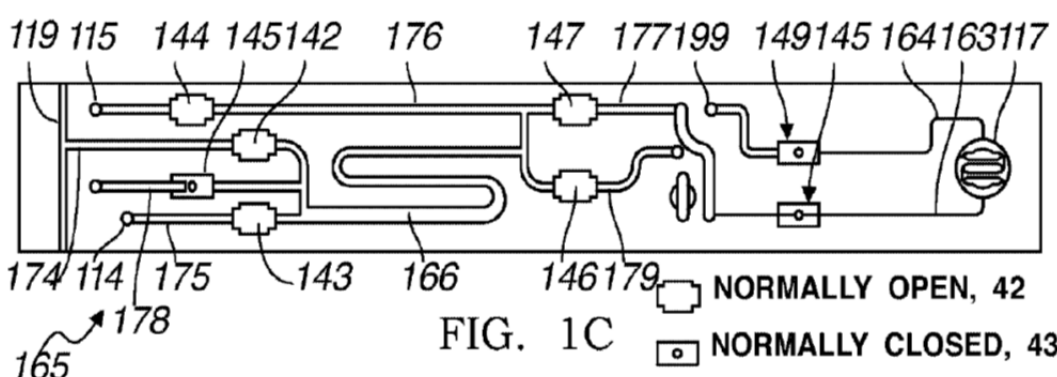
Claim	Claim Language	Infringement Evidence
		<p>the second pair of surfaces and proximal to the first layer, having a set of openings for occlusion of the fluidic pathway at the set of occlusion positions, and wherein occluding the fluidic pathway at a first subset of the set of occlusion positions defines a truncated pathway configured to facilitate transfer of waste fluid of the sample to the waste chamber.</p> <ul style="list-style-type: none"> • Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate. • Claim 15. The cartridge of claim 8, wherein at least one void of the set of voids defined by the corrugated surface of the waste chamber is a rectangular prismatic void spanning a long dimension of the cartridge and defining a magnet housing region configured to cross the first fluidic pathway and the second fluidic pathway. • Claim 16. The cartridge of claim 8, wherein the elastomeric layer is situated between the first layer and the intermediate substrate, wherein the intermediate substrate provides access to a set of occlusion positions of the first fluidic pathway and of the second fluidic pathway by way of the set of voids of the corrugated surface of the waste chamber, such that the first fluidic pathway and the second fluidic pathway are configured to be occluded upon deformation of the elastomeric layer at subsets of the set of occlusion positions, and wherein the waste chamber is located inferior to the elastomeric layer. • Claim 17. The cartridge of claim 16, wherein the first fluidic pathway is configured to transfer a first waste fluid of the sample to the waste chamber through a first waste inlet, upon occlusion of a first subset of the set of occlusion positions, by way of a first waste segment fluidly coupled to the first waste inlet and a first portion of the first fluidic pathway proximal the first sample port, and wherein the first fluidic pathway is configured to transfer a second waste fluid of the sample to the waste chamber through a second waste inlet, upon occlusion of a second subset of the set of occlusion positions, by way of a second waste segment fluidly coupled to the second waste inlet and a second portion of the first fluidic pathway substantially downstream of the first sample port.

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • Claim 18. The cartridge of claim 16, wherein the first fluidic pathway is configured to transfer a first waste fluid to the waste chamber through a first waste inlet, upon occlusion of a first subset of the set of occlusion positions, by way of a first waste segment fluidly coupled to the first waste inlet and inline with the first fluidic pathway, and wherein the second fluidic pathway is configured to transfer a second waste fluid to the waste chamber through a second waste inlet, upon occlusion of a second subset of the set of occlusion positions, by way of a second waste segment fluidly coupled to the second waste inlet and inline with the second fluidic pathway. • U.S. Patent No. 9,403,165 at 2:39-3:6 (“As shown in FIGS. 1A-1C, an embodiment of a microfluidic cartridge 100 for processing and detecting nucleic acids comprises: a top layer 110 comprising a set of sample port-reagent port pairs 112 and a set of detection chambers 116; an intermediate substrate 120, coupled to the top layer 110 and partially separated from the top layer by a film layer 125, configured to form a waste chamber 130; an elastomeric layer 140 partially situated on the intermediate substrate 120; a magnet housing region 150 accessible by a magnet 152 providing a magnetic field 156; and a set of fluidic pathways 160, each formed by at least a portion of the top layer 110, a portion of the film layer 125, and a portion of the elastomeric layer 140. In other embodiments, the microfluidic cartridge 100 may further comprise a bottom layer 170 coupled to the intermediate substrate 120 and configured to seal the waste chamber 130. Furthermore, the top layer 110 of the microfluidic cartridge 100 may further comprise a shared fluid port 118, a vent region 190, and a heating region 195, such that each fluidic pathway 165 in the set of fluidic pathways 160 is fluidically coupled to a sample port-reagent port pair 113, the shared fluid port 118, the waste chamber 130, and a detection chamber 117, comprises a capture segment 166 configured to pass through the heating region and the magnetic field, and is configured to pass through the vent region 190 upstream of the detection chamber 117. Each fluidic pathway 165 thus functions to receive and facilitate processing of a sample fluid containing nucleic acids as it passes through different portions of the fluidic pathway 165. As configured, the microfluidic cartridge 100 can be used to facilitate molecular diagnostic processes and techniques, and preferably conforms to microtiter plate dimensional standards. Alternatively, the microfluidic cartridge 100 may be any appropriate size. In a specific application, the microfluidic cartridge 100 can be used to facilitate a PCR procedure for analysis of a sample containing nucleic acids.”) • U.S. Patent No. 9,403,165 at FIG. 1A.

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		 <p data-bbox="1081 982 1255 1023">FIG. 1A</p> <ul data-bbox="615 1044 1984 1295" style="list-style-type: none"> • U.S. Patent No. 9,403,165 at 8:24-32 (“As shown in FIG. 1B, an embodiment of the microfluidic cartridge also comprises an intermediate substrate 120, coupled to the top layer 110 and partially separated from the top layer 110 by a film layer 125, configured to form a waste chamber 130. The intermediate substrate 120 functions to serve as a substrate to which layers of the microfluidic cartridge may be bonded, to provide guides for the valve pins, and to provide a waste chamber volume into which a waste fluid may be deposited.”) • U.S. Patent No. 9,403,165 at FIG. 1B.

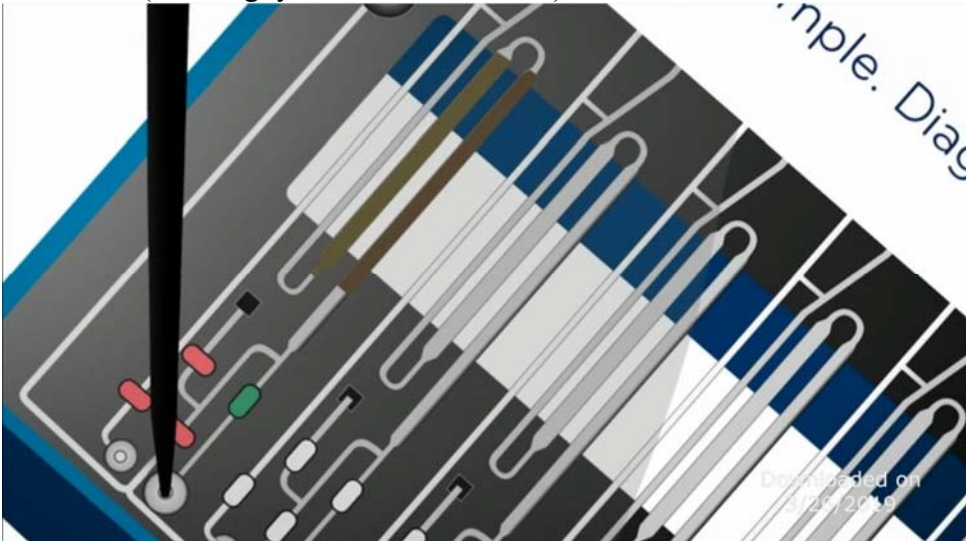
Claim	Claim Language	Infringement Evidence
		<div data-bbox="667 240 1587 570" data-label="Image"> <p style="text-align: center;">FIG. 1B</p> </div> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at 9:57-10:21 (“As shown in FIG. 1B, the intermediate substrate 120 of an embodiment of the microfluidic cartridge 100 is configured to form a waste chamber 130, which functions to receive and isolate waste fluids generated within the microfluidic cartridge 100. The waste chamber 130 is preferably continuous and accessible by each fluidic pathway 165 of the microfluidic cartridge 100, such that all waste fluids generated within the microfluidic cartridge 100 are deposited into a common waste chamber; however, each fluidic pathway 165 of the microfluidic cartridge 100 may alternatively have its own corresponding waste chamber 130, such that waste fluids generated within a fluidic pathway 165 of the microfluidic cartridge 100 are isolated from waste fluids generated within other fluidic pathways 165 of the microfluidic cartridge 100. In a specific embodiment of the microfluidic cartridge 100 with a continuous waste chamber, the waste chamber has a volumetric capacity of approximately 25 mL; however, the waste chamber 130 of another embodiment may have a different volumetric capacity. The intermediate substrate 120 further comprises a waste vent 135, which provides access between a microfluidic channel of a fluidic pathway 165 above the film layer 125 and the waste chamber 130. Preferably, the intermediate substrate 120 comprises more than one waste inlet 136, such that the waste chamber is accessible at more than one location along a fluidic pathway 165 through the waste inlets 136. Alternatively, the intermediate substrate 120 may include a single waste inlet 136, such that all waste fluids generated within the microfluidic cartridge 100 are configured to travel through the single waste inlet 136 into the waste chamber 130. Also, as shown in FIG. 1B, the intermediate substrate 120 may comprise a waste vent 131, such that the waste chamber 130 is vented to prevent pressure build up in the waste chamber as waste fluid is added.”) U.S. Patent No. 9,403,165 at 13:23-51 (“The set of fluidic pathways 160 of the microfluidic cartridge 100 functions to provide a fluid network into which volumes of sample fluids, reagents, buffers and/or gases used in a molecular diagnostics protocol may be delivered, out of which waste fluids may be

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		<p>eliminated, and by which processed nucleic acid samples may be delivered to a detection chamber for analysis, which may include amplification and/or detection. Preferably, each fluidic pathway 165 in the set of fluidic pathways 160 is formed by at least a portion of the top layer, a portion of the film layer, and a portion of the elastomeric layer 140, such that each fluidic pathway 165 may be occluded upon deformation of the elastomeric layer 140 at a set of occlusion positions 141. Additionally, at least one fluidic pathway 165 in the set of fluidic pathways 160 is preferably fluidically coupled to a sample port-reagent port pair 113 of the set of sample port-reagent port pairs 112, a fluid port 118, a waste chamber 130, and a detection chamber 117 of the set of detection chambers 116. Furthermore, at least one fluidic pathway 165 in the set of fluidic pathways 160 is preferably configured to be occluded upon deformation of the elastomeric layer 140, configured to transfer a waste fluid to the waste chamber 30, comprises a capture segment 166 passing through the heating region 195 and a magnetic field 156, and is configured to pass through the vent region 190 upstream of a detection chamber 117. Alternative embodiments may omit preferred elements of the embodiment of the fluidic pathway 165 described above, such as a vent region 190 or a heating region 195, or add additional elements to the embodiment of the fluidic pathway 165 described above.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,403,165 at 14:39-56 (“As shown in FIGS. 1C, 6C, 7 and 9, a fluidic pathway 165 of the set of fluidic pathways 160 is branched and preferably comprises an initial segment 174 fluidically coupled to a fluid channel 119 coupled to a fluid port 118, a sample segment 175 coupled to a sample port 114, a reagent segment 176 coupled to a reagent port 115, a capture segment 166 passing through at least one of the heating region 195 and a magnetic field 156, a vent segment 177 configured to pass through the vent region 190, a segment running to a detection chamber 163, a segment running away from the detection chamber 164, and at least one waste segment 178, 179 configured to transfer a waste fluid to a waste chamber 130. Individual segments of the fluidic pathway 165 are preferably configured to pass through at least one occlusion position of the set of occlusion positions 141, to controllably direct fluid flow through portions of the fluidic pathway 165. A fluidic pathway 165 may also further comprise an end vent 199, which functions to prevent any fluid from escaping the microfluidic channel.”) • U.S. Patent No. 9,403,165 at 15:22-51 (“A first embodiment, as shown in FIG. 1C, of a fluidic pathway 165 preferably comprises an initial segment 174 fluidically coupled to a fluid channel 119 coupled to a shared fluid port 118, a sample segment 175 coupled to a sample port 114 and to the initial segment 174, and an s-shaped capture segment 166, configured to pass through the heating region 195 and a magnetic field 156, coupled to the initial segment 174 and the sample segment 175. In a variation of the first embodiment, the s-shaped capture segment 166 may comprise an initial wide arc 166 to provide a greater

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		<p>surface area for magnetic bead capture. In another variation of the first embodiment, the capture segment 166 may alternatively be a progressively narrowing s-shaped capture segment 166. The first embodiment of the fluidic pathway 165 also comprises a reagent segment 176 coupled to a reagent port 115 and to the capture segment 166, a vent segment 177 coupled to the reagent segment 176 and configured to pass through the vent region 190, a segment running to a detection chamber 163 from the vent region 190, a winding segment running away from the detection chamber 164, and an end vent 199 coupled to the segment running away from the detection chamber 164. The first embodiment of the fluidic pathway 165 also comprises a first waste segment 178 configured to couple the initial segment 174 to the waste chamber 130, and a second waste segment 179 configured to couple the capture segment 166 to the waste chamber 130. The first waste segment 178 preferably functions to allow evacuation of excess release fluids from a fluidic pathway 165, for precise metering of the amount of release reagents used in a molecular diagnostic procedure using a low volume of sample.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at FIG. 1C.  <p>FIG. 1C</p> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at 16:7-23 (“The occlusion positions of the set of occlusion positions 141 of the first embodiment are preferably located such that occluding subsets of the set of occlusion positions 141 defines unique truncated fluidic pathways to controllably direct fluid flow. For example, as shown in FIG. 1D, occluding the fluidic pathway 165 at the first, third, fourth, and sixth occlusion positions 142, 144, 145, 147 forms a truncated pathway by which a volume of a sample fluid, comprising nucleic acids bound to magnetic beads and delivered into the sample port 114, may flow past the second occlusion positions 143 into the capture segment 166 for isolation and purification of nucleic acids using the heating region 195 and the magnetic field 156. Nucleic acids bound to magnetic beads may thus be trapped within

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		<p>the capture segment 166 by the magnetic field 156, while other substances in the volume of sample fluid may pass into the waste chamber 130 by passing the fifth occlusion position 146.’’)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at 18:40-65 (“The occlusion positions of the set of occlusion positions 141’ of the second embodiment are preferably located such that occluding of subsets of the set of occlusion positions 141’ defines unique truncated fluidic pathways to controllably direct fluid flow. For example, occluding the fluidic pathway 165’ at the first, fourth, sixth, tenth, and eleventh occlusion positions 142’, 145’, 147’, 158’, 159’ forms a truncated pathway by which a volume of a sample fluid, comprising nucleic acids bound to magnetic beads and delivered into the sample port 114, may flow into the capture segment 166’ for isolation and purification of nucleic acids using the heating region 195 and the magnetic field 156. Nucleic acids bound to magnetic beads may thus be trapped within the capture segment 166’ by the magnetic field 156, while other substances in the volume of sample fluid may pass into the waste chamber 130 by passing the fifth occlusion position 146’. Following this subset of occlusion positions, the occlusion at the first occlusion position 142’ may be reversed, and the fluidic pathway 165’ may be occluded at the second occlusion position 143’ to form a second truncated pathway by which a wash fluid may be delivered through the fluid port 118, into the capture segment 166’ (thus washing the trapped magnetic beads), and into the waste chamber 130 by passing the fifth occlusion position 146’. A volume of air may then be pumped through the fluid port 118 to flush any remaining wash solution into the waste chamber 130.’’) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and

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		<p>align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 22:29-60 (“The microfluidic cartridge 210 functions to receive a set of magnetic bead-samples, facilitate separation of nucleic acids from the set of magnetic bead-samples, receive a set of nucleic acid-reagent samples, and facilitate analysis of nucleic acids from the set of nucleic acid-reagent samples. In one embodiment, the microfluidic cartridge 210 comprises a top layer 211 including a set of sample port-reagent port pairs 212 and a set of detection chambers 213; an intermediate substrate 214, coupled to the top layer 211 and partially separated from the top layer 211 by a film layer 215, configured to form a waste chamber 216; an elastomeric layer 217 partially situated on the intermediate substrate 214; a magnet housing region 218 accessible by a magnet 160 providing a magnetic field; and a set of fluidic pathways 219, each formed by at least a portion of the top layer 211, a portion of the film layer 215, and a portion of the elastomeric layer 217. In the embodiment, the microfluidic cartridge 10 further comprises a bottom layer 221 coupled to the intermediate substrate 214 and configured to seal the waste chamber 216. Furthermore, in the embodiment, the top layer 211 of the microfluidic cartridge 210 further comprises a shared fluid port 222, a vent region 223, and a heating region 224, such that each fluidic pathway 220 in the set of fluidic pathways 219 is fluidically coupled to a sample port-reagent port pair 224, the shared fluid port 222, the waste chamber 216, and a detection chamber 225, comprises a turnabout portion 226 configured to pass through the heating region 224 and the magnetic field, and is configured to pass through the vent region 223 upstream of the detection chamber 225. Each fluidic pathway 220 thus functions to receive and facilitate processing of a sample fluid containing nucleic acids as it passes through different portions of the fluidic pathway 220.”) • U.S. Patent No. 9,050,594 at 30:8-27 (“In a specific example of Step S440, the set of fluidic pathways containing a set of nucleic acid-magnetic bead samples, from the specific example of Step S430, is occluded at a subset of the set of occlusion positions by a valve actuation subsystem of the molecular diagnostic module, to define a set of truncated fluidic pathways coupled to a waste chamber and to a shared fluid port of the microfluidic cartridge for delivery of a wash solution and a release solution. The liquid handling system delivers a wash fluid through the shared fluid port to wash the set of nucleic acid-

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		<p>magnetic bead samples, captured within the magnetic field, and then delivers a release fluid through the shared fluid port to release a set of nucleic acid volumes from the set of nucleic acid-magnetic bead samples. In the specific example, each fluidic pathway is washed sequentially, and the release solution is delivered to each fluidic pathway sequentially to ensure that each lane is provided with substantially equal amounts of wash and release solutions. All waste fluid produced in the specific example of Step S440 pass into the waste chamber coupled to the set of truncated fluidic pathways.”)</p>
1(f)	<p>a magnetic separator configured to apply a magnetic force to at least one process chamber of the plurality of process chambers in the first module</p>	<p>In the accused system, the first module comprises, a magnetic separator configured to apply a magnetic force to at least one process chamber of the plurality of process chambers in the first module.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” <i>Id.</i> at 2:28-2:39. • <i>Id.</i> at 2:28 (showing lysate in the s-channel). 

Claim	Claim Language	Infringement Evidence
		<p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> • Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10. • Claim 2. The method of claim 1, wherein receiving the binding moiety solution, comprising the set of affinity moiety-coated microparticles, within the process chamber comprises receiving a set of magnetic microparticles, each magnetic microparticle modified with an amine-reactive ester functional group configured to react with one of a set of amine groups of a molecule of Polypropylenimine tetramine dendrimer Generation 1. • Claim 3. The method of claim 1, wherein receiving the binding moiety solution, comprising the set of affinity moiety-coated microparticles, comprises receiving a set of magnetic microparticles covalently bonded to a set of affinity moiety molecules, and wherein contacting the binding moiety solution with the biological sample comprises aspirating the binding moiety solution along with the biological sample from the process chamber and dispensing the binding moiety solution with the biological sample to the process chamber. • Claim 5. The method of claim 3, wherein separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises magnetically separating the set of moiety-bound nucleic acid

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		<p>particles from the moiety-sample mixture.</p> <ul style="list-style-type: none"> • Claim 6. The method of claim 5, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety-sample mixture from the process chamber; occluding the fluidic pathway of the cartridge-at a set of occlusion positions upon displacement of pins of the set of pins to generate a path through a magnetic field, and to a waste chamber; and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber. • Claim 10. The method of claim 3, wherein washing the set of moiety-bound nucleic acid particles comprises aspirating the moiety-sample mixture; receiving the cartridge at the cartridge receiving module comprising the set of pins and a cam card interfacing with the set of pins; transitioning the cartridge to an active configuration that disposes the cartridge proximal the set of pins; displacing the first subset of the set of pins in the active configuration of the cartridge, upon translation of the cam card relative to the set of pins, thereby occluding the fluidic pathway of the cartridge at a set of occlusion positions; delivering the moiety-sample mixture into the fluidic pathway, wherein the fluidic pathway is configured to pass through a magnetic field and is coupled to a waste chamber, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field; and delivering a wash solution through the fluidic pathway and into the waste chamber in a continuous flow operation.. • Claim 13. The method of claim 3, wherein releasing the nucleic acid sample from the set of moiety-bound nucleic acid particles comprises occluding the fluidic pathway of the cartridge, comprising the process chamber, at a set of occlusion positions, upon displacement of pins of the set of pins, to define a path through a magnetic field; delivering the set of moiety-bound nucleic acid particles into the path of the fluidic pathway; and delivering an elution solution into the fluidic pathway, thereby inducing a pH shift configured to release the nucleic acid sample from the set of moiety-bound nucleic acid particles. • Claim 14. The method of claim 13, further comprising capturing the set of moiety-bound nucleic acid particles within the magnetic field and aspirating the nucleic acid sample from the fluidic pathway. • Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a

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		<p>biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second subset of the set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction.</p> <ul style="list-style-type: none"> • Claim 18. The method of claim 17, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety-sample mixture from the process chamber; occluding the fluidic pathway of the cartridge at a set of occlusion positions upon displacement of the first subset of the set of pins to generate a path through a magnetic field, and to a waste chamber of the cartridge; and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber. • Patent No. 9,382,532 at 4:35-44 (“In a specific example of this variation of Step S110, the microparticles are magnetic beads (e.g., magnetic, paramagnetic [sic], superparamagnetic) with any suitable hydrophilicity (e.g., hydrophobic, hydrophilic), wherein the magnetic beads are coated with the affinity moiety and simultaneously received within the process chamber along with a low-pH buffer solution, proteolytic enzymes, and lytic reagents. In this specific example, magnetic separation can be used to facilitate further processing and isolation of nucleic acids bound to the affinity moieties coupled to magnetic beads.”) • Patent No. 9,382,532 at 6:41-67 (“Step S140 recites separating the moiety-bound nucleic acid volume from the waste volume, and functions to compact or concentrate microparticles coupled to the target nucleic acid(s), by way of the affinity moieties, in order to facilitate removal of the waste volume from the moiety-bound nucleic acid volume. Preferably, the moiety-bound nucleic acid volume is separated using a magnetic-separation method; however the moiety-bound nucleic acid volume can alternatively be separated using methods based upon microparticle size, mass, and/or density (e.g., centrifugation,

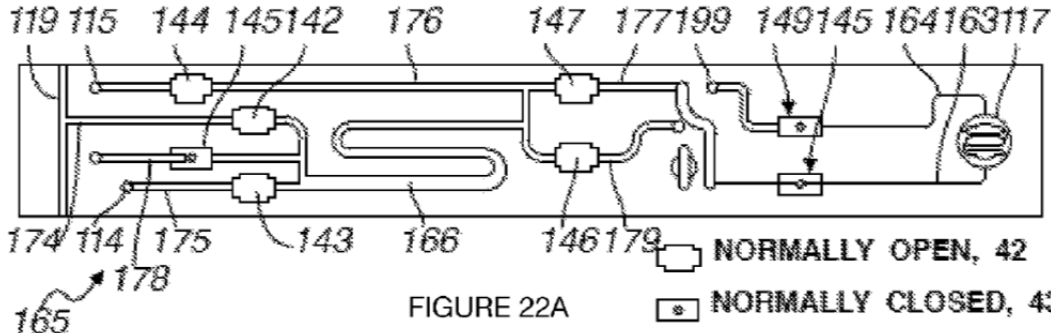
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		<p>sedimenting, filtering), and/or focusing methods (e.g., electric field focusing, laser based focusing). Separation in Step S140 can, however, be performed using any other suitable method. In a first variation, wherein the microparticles coupled with affinity moieties have magnetic properties, a magnetic field can be applied to retain the nucleic acid-bound microparticles of the moiety-bound nucleic acid volume, while the waste volume (e.g., cellular debris and other unbound material) is substantially removed by aspiration. In a second variation, wherein the microparticles coupled with affinity moieties have a characteristic dimension for size-based separation, the lysed moiety-sample solution can be filtered to substantially remove the waste volume. In the second variation, the filter is preferably configured to pass the microparticles bound to the target nucleic acids while retaining the waste; however, the filter can alternatively be configured to retain the microparticles while passing the waste.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at 7:14-53 (“In Step S140, the lysed moiety-sample solution can be processed within the process chamber to separate the moiety-bound nucleic acid volume from the waste volume; however, the lysed moiety-sample solution can alternatively be transferred to another suitable vessel for separation of the moiety-bound nucleic acid volume from the waste volume. In a first variation, a pipetting system (automatic or manual) can be used to remove the waste volume (e.g., supernatant liquid), and multiple aspirations by the pipetting system may be necessary to ensure as complete a removal of the supernatant as possible. In an example of the first variation, a 1000 micro liter pipette tip can be used to perform gross removal of the waste volume in a first aspiration followed by the use of a finer pipette tip (e.g., 100-200 microliter tip) in additional aspirations, to remove the remainder of the waste volume. In the example, the removal of the waste volume occurs close to the bottom of the process chamber to provide complete liquid removal with minimal bubbling. In a second variation, the lysed moiety-sample solution can be transferred to a vessel that enables the moiety-bound nucleic acid volume to be captured and the waste volume to be removed in a flow through manner, either against the pores of a filter or in the presence of a magnetic field. In the second variation, the microparticles with bound nucleic acids are retained in a filter zone or a magnetic field zone of the vessel, and the liquid portion is flowed into a "waste chamber". In a specific example of the second variation, a system (such as the one described in U.S. patent application Ser. No. 13/766,359, entitled "System and Method for Processing and Detecting Nucleic Acids") can be used to transfer the lysed moiety-sample solution into a fluidic pathway of a cartridge (such as the one described in U.S. patent application Ser. No. 13/765,996, entitled "Microfluidic Cartridge for Processing and Detecting Nucleic Acids"). In the specific example, the lysed moiety-sample solution can be retained by a magnetic field within a portion of the fluidic

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		<p>pathway upon occlusion of the fluidic pathway at a suitable set of occlusion positions, in order to separate the moiety-bound nucleic acid volume from the waste volume. The waste volume can then be removed by pushing the waste volume to a waste chamber of the cartridge.”)</p> <ul style="list-style-type: none"> • Patent No. 9,382,532 at 8:5-10 (“Furthermore, the microparticles of the moiety-bound nucleic acid volume can be agitated to go back into a suspension from a compacted state (e.g., during magnetic capture) or the wash solution can simply be flowed over the microparticles to further remove non-specific moieties and facilitate exchange of buffers.”) • Patent No. 9,382,532 at 8:41-55 (“In a variation of the first example of Step S150, a system (such as the one described in U.S. patent application Ser. No. 13/766,359, entitled "System and Method for Processing and Detecting Nucleic Acids") can be used to deliver the wash solution into a fluidic pathway of a cartridge (such as the one described in U.S. patent application Ser. No. 13/765,996, entitled "Microfluidic Cartridge for Processing and Detecting Nucleic Acids"). In the variation of the first example, the microparticles of the moiety-bound nucleic acid volume can be retained by a magnetic field within a portion of the fluidic pathway upon occlusion of the fluidic pathway at a suitable set of occlusion positions, and the wash solution can be delivered through the portion of the fluidic pathway and into a waste chamber of the cartridge to wash the microparticles with the bound target nucleic acid(s).”) • Patent No. 9,382,532 at 9:63-10:13 (“In a specific example of Steps S160 and S161, a system (such as the one described in U.S. patent application Ser. No. 13/766,359, entitled "System and Method for Processing and Detecting Nucleic Acids") can be used to deliver the elution solution into a fluidic pathway of a cartridge (such as the one described in U.S. patent application Ser. No. 13/765,996, entitled "Microfluidic Cartridge for Processing and Detecting Nucleic Acids"). In the variation of the specific example, the microparticles of the moiety-bound nucleic acid volume can be retained by a magnetic field within a portion of the fluidic pathway upon occlusion of the fluidic pathway at a suitable set of occlusion positions, and the elution solution can be delivered through the portion of the fluidic pathway enable release of the nucleic acid sample from the microparticle. Additionally, a heating element of the system can be moved proximal to the portion of the fluidic pathway with the elution solution and the microparticles to further enhance release of the nucleic acid sample.”) • Patent No. 9,382,532 at 11:6-23 (“In a specific example of this variation, a system (such as the one described in U.S. patent application Ser. No. 13/766,359, entitled "System and Method for Processing and Detecting Nucleic Acids") can be used to aspirate the nucleic acid sample from a fluidic path way of a cartridge (such as the one described in U.S. patent application Ser. No. 13/765,996, entitled "Microfluidic Cartridge for Processing and Detecting Nucleic Acids"), while the microparticles are

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		<p>immobilized by a magnet. The system can then combine the nucleic acid sample with process reagents (e.g., PCR reagents) in a separate container (e.g., assay plate), and then transfer the nucleic acid sample combined with process reagents to a detection chamber of the fluidic pathway (upon occlusion and/or opening of the fluidic channel at another subset of occlusion positions). The nucleic acid sample combined with process reagents can then be processed within a diagnostic chamber that is coupled to the fluidic pathway.”)</p> <ul style="list-style-type: none"> • Patent No. 9,382,532 at 12:51-61 (“The affinity moieties, such as the PAA and DABAM described in Section 2.1 and 2.2, can be immobilized on a suitable substrate to facilitate subsequent capture of target nucleic acids bound to the substrate (e.g., by magnetic separation, size-based separation, density-based separation, or focusing). A process for coupling the affinity moiety to the substrate preferably relies on creation of a covalent bond between the affinity moiety and the microparticle, and in one variation as described below, a carboxylic acid group (-COOH) can be used to form the covalent bond between the microparticles and the affinity moieties”) • Patent No. 9,382,532 at 13:7-13 (“The method 200 functions to produce a set of moiety-bound microparticles for nucleic acid isolation. Preferably, the microparticles are magnetic to facilitate nucleic acid isolation by magnetic separation; however, the microparticles can alternatively be characterized by any suitable feature that facilitates nucleic acid isolation, as described earlier in Section 1.”) • Patent No. 9,382,532 at 13:14-28 (“In a specific example, as shown in FIG. 3, the method 200 comprises activating magnetic carboxylated microparticles with EDAC in Step S110 to form a set of magnetic microparticle-reactive ester compounds; treating the set of magnetic microparticle-reactive ester compounds with a N-Hydroxysulfosuccinimide to form a set of microparticle-amine reactive ester compounds S220; combining the set of microparticle- amine reactive ester compounds with a set of affinity moieties selected from the group comprising PAA of molecu- lar weight less than 30,000 Da and DABAM of generation less than two S230 to produce a microparticle-moiety solution; and repeatedly washing the microparticle-moiety solution, thereby producing a set of magnetic microparticles covalently bonded to the set of affinity moieties by amide bonds S240.”) • Patent No. 9,382,532 at 13:42-14:2 (“A first example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, cerebrospinal fluid (CSF) as a representative biological sample, and Enterovirus (EV) viral particles as the model target. In the first example, 200 μL of CSF was spiked with 2 μL of EV viral particle lysate and then mixed with 500 μL of RNA Collection Buffer 1 (CBR-1) and 300 μL of nuclease-free water in examples of Steps S110 and S120. As a comparison, a

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		<p>similar amount of EV particle lysate was spiked into a 1 mL solution comprised of 500 µL of CBR-1 buffer and 500 µL of nuclease-free water and processed simultaneously. In an example of Step S130, RNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 60 C. Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 500 µL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160. Isolated RNA was eluted into 10 µL of EL U-2 and 8 µL of the eluate was used for real-time RT-PCR in an example of Step S170. As shown in FIG. 4, results of the RNA isolation as elucidated by a real-time Enterovirus RT-PCR assay indicate that the RNA isolation process is substantially equally efficient in the biological sample matrix as compared to a simple buffer sample. This indicates that the example method 100 and the nucleic acid isolation reagents are efficacious at capture, release and cleanup of the target RNA in CSF matrix in the first example.”)</p> <ul style="list-style-type: none"> Patent No. 9,382,532 at 14:5-38 (“A second example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, M4 transport medium containing a nasal swab (donor) as a representative biological sample, and Enterovirus (EV) viral particles as the model target. In the second example, 500 µL of M4 transport media containing a nasal swab (donor) was spiked with 2 µL of either a 10⁻² dilution (high) or a 10⁻⁴ (low) dilution of EV RNA (purified from 200 µL viral particle lysate and eluted in 20 µL total volume) and then mixed with 500 µL of RNA Collection Buffer 1 (CBR-1) and 0.4 mg of Proteinase Kin examples of Steps S110 and S120. RNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for minutes at 60 C in an example of Step S130. Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2x) with 250 µL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160. RNA was then eluted into 10 µL of ELU-2 and 8 µL of the eluate was used for real-time RT-PCR in an example of Step S170. As a comparison, a similar amount of EV RNA was used directly in real-time RT-PCR at both low and high input levels as a reference, which would correlate to an extraction efficiency of 100%. As shown in FIG. 5, results of the RNA isolation as elucidated by a real-time Enterovirus RT-PCR assay indicate that the RNA isolation process is efficient in the biological sample matrix as compared to the input PCR control samples that were not subject to the full extraction process. A small shift in the amplification of the extracted samples does not necessarily indicate a loss in extraction efficiency or sensitivity. This indicates that the example method 100 and the nucleic acid isolation reagents are efficacious at capture, release and cleanup of the target RNA in M4 transport media

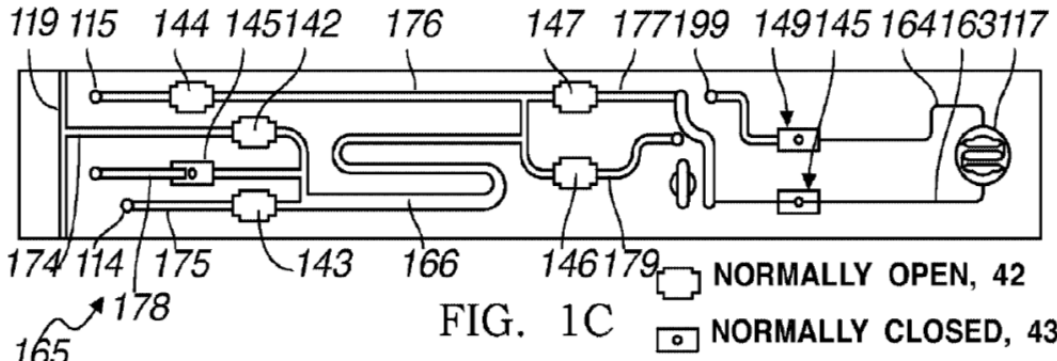
Claim	Claim Language	Infringement Evidence
		<p>matrix.”)</p> <ul style="list-style-type: none"> • Patent No. 9,382,532 at 20:60 - 21:20 (“Preferably, variations of the method 100 for plasma nucleic acid extractions comprise eluting into a 20 uL elution volume, providing 40 uL of 20 mg/mL Proteinase K in a lysis solution, providing a salt wash (e.g. 150 mM NaCl in 1 mM Tris pH 8.0), using AptaTaq polymerase, and providing a longer elution time (e.g., 5-10 minutes). However, in other variations of the twelfth through fourteenth examples, the example method 100 can comprise any suitable combination of: using any suitable volume of an elution solution (e.g., 10 uL-25 uL elution solution), providing any suitable composition of an elution solution (e.g., 20 mM Na OH, 40 mM Na OH, KOH), providing a lysis solution with any suitable amount of Proteinase K (e.g., +/-20-40 uL of 20 mg/mL Proteinase K), using any suitable polymerase (e.g., Native Taq, AptaTaq), using fresh or frozen plasma, eluting at any suitable temperature (e.g., room temperature to 85 C), using magnetic microparticles of any hydrophilicity (e.g., hydrophilic, hydrophobic), using any suitable amount of affinity moiety (e.g., 100-3000 ug of PAA) in any suitable volume (e.g., 30 uL), providing any suitable wash solution (e.g, 1 mM TRIS pH 8 with 50-200 mM NaCL, 200 mM KC! in 10 mM TRIS pH 8, 10 mM TRIS pH 8 with 0.1 % tween and IM NaCl, 0.5% SDS in 1 mM TRIS pH 8, 200 mM NaCl in 1 mM TRIS pH 8), resuspending magnetic microparticles in a release buffer, not resuspending magnetic microparticles in a release buffer, and providing any suitable denaturation temperatures (e.g., 85-95 C) and/or anneal temperatures (55-60 C) during processing for PCR.”) • Patent No. 9,382,532 at 24:1-12 (“A first illustration of the eighteenth example, as shown in FIG. 22A, of a fluidic pathway 165 preferably comprises an initial segment 174 fluidically coupled to a fluid channel 119 coupled to a shared fluid port 118, a sample segment 175 coupled to a sample port 114 and to the initial segment 174, and an s-shaped capture segment 166, configured to pass through the heating region 195 and a magnetic field 156, coupled to the initial segment 17 4 and the sample segment 175. In an alternative illustration of the eighteenth example, the s-shaped capture segment 166 may comprise an initial wide arc 166 to provide a greater surface area for magnetic bead capture.”) • Patent No. 9,382,532 at FIG. 22A.

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		 <p data-bbox="1087 537 1255 565">FIGURE 22A</p> <p data-bbox="1339 532 1738 565">□ NORMALLY OPEN, 42 ◻ NORMALLY CLOSED, 43</p> <ul style="list-style-type: none"> Patent No. 9,382,532 at 24:53-25:16 (“The occlusion positions of the set of occlusion positions 141 of the first illustration are preferably located such that occluding subsets of the set of occlusion positions 141 defines unique truncated fluidic pathways to controllably direct fluid flow. For example, as shown in FIG. 22B, occluding the fluidic pathway 165 at the first, third, fourth, and sixth occlusion positions 142, 144, 145, 147 forms a truncated pathway by which a volume of a sample fluid, comprising nucleic acids bound to magnetic beads and delivered into the sample port 114, may flow past the second occlusion positions 143 into the capture segment 166 for isolation and purification of nucleic acids using the heating region 195 and the magnetic field 156. Nucleic acids bound to magnetic beads may thus be trapped within the capture segment 166 by the magnetic field 156, while other substances in the volume of sample fluid may pass into the waste chamber 130 by passing the fifth occlusion position 146. Following this subset of occlusion positions, the occlusion at the first occlusion position 142 may be reversed, as shown in FIG. 22C, and the fluidic pathway 165 may be occluded at the second occlusion position 143 to form a second truncated pathway by which a wash fluid may be delivered through the fluid port 118, into the capture segment 166 (thus washing the trapped magnetic beads), and into the waste chamber 130 by passing the fifth occlusion position 146. The occlusion at the second occlusion position 143 may then be reversed, and the first occlusion position 142 may be occluded (as shown in FIG. 22B), so that other fluidic pathways in the set of fluidic pathways 160 may be washed. After all fluidic pathways have been washed, a volume of air may be transferred through the fluid port 118 to prevent mixture of a wash solution with a release solution.”) Patent No. 9,382,532 at 25:30-50 (“Thereafter, the occlusion at the fourth occlusion position 145 maybe reversed, creating a fifth truncated pathway, and release solution within the fluidic pathway 165 may be metered by pumping air through the fluid port 118, which functions to push a portion of the release

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		<p>solution into the waste chamber 130. A volume of release solution will still be maintained within the capture segment 166 at this stage. The first and the fourth occlusion positions 142, 145 may then be occluded to form a sixth truncated pathway sealing the volume of release solution, with the captured magnetic beads bound to nucleic acids, within the capture segment 166. The volume of the remaining release solution is therefore substantially defined by the microchannel volume between junctions in the fluidic pathway 165 near the fourth and sixth occlusion positions 145, 147, and maybe any small volume but in a specific variation is precisely metered to be 23+/-1 microliters. Release solution may be sealed within capture segments of other fluidic pathways using a similar process. A heater may then be provided at the sixth truncated pathway, inducing a pH shift within the sixth truncated pathway to unbind nucleic acids from the magnetic beads.")</p> <ul style="list-style-type: none"> • Patent No. 9,382,532 at 26:28-34 ("A second illustration of the eighteenth example, of a fluidic pathway 165' preferably comprises an initial segment 174 fluidically coupled to a fluid channel 119' coupled to a shared fluid port 118', a sample segment 175' coupled to a sample port 114' and to the initial segment 174', and a capture segment 166', configured to pass through the heating region 195 and a magnetic field 156, coupled to the initial segment 174'.") • Patent No. 9,382,532 at 27:17-42 ("The occlusion positions of the set of occlusion positions 141' of the second illustration are preferably located such that occluding of subsets of the set of occlusion positions 141' defines unique truncated fluidic pathways to controllably direct fluid flow. For example, occluding the fluidic pathway 165' at the first, fourth, sixth, tenth, and eleventh occlusion positions 142', 145', 147', 158', 159' forms a truncated pathway by which a volume of a sample fluid, comprising nucleic acids bound to magnetic beads and delivered into the sample 25 port 114, may flow into the capture segment 166' for isolation and purification of nucleic acids using the heating region 195 and the magnetic field 156. Nucleic acids bound to magnetic beads may thus be trapped within the capture segment 166' by the magnetic field 156, while other substances in the volume of sample fluid may pass into the waste chamber 130 by passing the fifth occlusion position 146'. Following this subset of occlusion positions, the occlusion at the first occlusion position 142' may be reversed, and the fluidic pathway 165' may be occluded at the second occlusion position 143' to form a second truncated pathway by which a wash fluid may be delivered through the fluid port 118, into the capture segment 166' (thus washing the trapped magnetic beads), and into the waste chamber 130 by passing the fifth occlusion position 146'. A volume of air may then be pumped through the fluid port 118 to flush any remaining wash solution into the waste chamber 130.") • Patent No. 9,382,532 at 27:43-28:2 ("Thereafter, in the second illustration, the fluidic pathway 165' may

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		<p>be occluded at the fifth occlusion position 146' and the occlusion at the tenth occlusion position 158' may be reversed, closing access to the waste chamber 130 and opening access to the end vent segment 197'. A release solution may then be delivered through the fluid port 118, into the capture segment 166', and to the end vent segment 197'. The volume of the release solution is therefore defined by the microchannel volume between the fourth and tenth occlusion positions 145', 158', and maybe any small volume but in a specific variation is precisely metered to be 15 microliters. Thereafter, occluding the fluidic pathway 165' at the tenth occlusion position 158', reversing the occlusion at the fourth occlusion position 145' (defining a fourth truncated pathway), and delivering air through the fluid port 118 pushes any remaining release buffer from the fluidic pathway 118 into the waste chamber 130, thereby ensuring that excess release buffer is not later exposed to nucleic acids bound to the magnetic beads (at this point, the nucleic acids are not substantially released from the magnetic beads because heat has not been added). Thereafter, the fluidic pathway 165' is occluded at the first and fourth occlusion positions 142', 145', defining a fifth truncated pathway comprising the capture segment 166', and the magnetic beads are heated to an appropriate temperature and time (e.g., 60 degrees for 5 minutes) within the heating region 195 to release the nucleic acids from the magnetic beads and into the release buffer.")</p> <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> • Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position of the fluidic pathway, by way of the void of the corrugated surface, the fluidic pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber. • Claim 3. The cartridge of claim 1, wherein the waste chamber comprises at least one waste inlet in communication with the opening of the intermediate substrate, and wherein the corrugated surface of the waste chamber further defines a rectangular prismatic void spanning a long dimension of the cartridge that defines a magnet housing region configured to reversibly receive a magnet from the direction perpendicular to a broad face of the first layer, and configured to cross the fluidic pathway.

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		<ul style="list-style-type: none"> • Claim 4. The cartridge of claim 3, wherein the fluidic pathway comprises a capture segment, downstream of the sample port and configured to cross the magnet housing region multiple times. • Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate. • Claim 15. The cartridge of claim 8, wherein at least one void of the set of voids defined by the corrugated surface of the waste chamber is a rectangular prismatic void spanning a long dimension of the cartridge and defining a magnet housing region configured to cross the first fluidic pathway and the second fluidic pathway. • U.S. Patent No. 9,403,165 at 2:39-3:6 (“As shown in FIGS. 1A-1C, an embodiment of a microfluidic cartridge 100 for processing and detecting nucleic acids comprises: a top layer 110 comprising a set of sample port-reagent port pairs 112 and a set of detection chambers 116; an intermediate substrate 120, coupled to the top layer 110 and partially separated from the top layer by a film layer 125, configured to form a waste chamber 130; an elastomeric layer 140 partially situated on the intermediate substrate 120; a magnet housing region 150 accessible by a magnet 152 providing a magnetic field 156; and a set of fluidic pathways 160, each formed by at least a portion of the top layer 110, a portion of the film layer 125, and a portion of the elastomeric layer 140. In other embodiments, the microfluidic cartridge 100 may further comprise a bottom layer 170 coupled to the intermediate substrate 120 and configured to seal the waste chamber 130. Furthermore, the top layer 110 of the microfluidic cartridge 100 may further comprise a shared fluid port 118, a vent region 190, and a heating region 195, such that each fluidic pathway 165 in the set of fluidic pathways 160 is fluidically coupled to a sample port-reagent port pair 113, the shared fluid port 118, the waste chamber 130, and a detection chamber 117, comprises a capture segment 166 configured to pass through the heating region and the magnetic field, and is configured to pass through the vent region 190 upstream of the detection chamber 117. Each fluidic pathway 165 thus functions to receive and facilitate processing of a sample fluid containing nucleic acids

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		<p>as it passes through different portions of the fluidic pathway 165. As configured, the microfluidic cartridge 100 can be used to facilitate molecular diagnostic processes and techniques, and preferably conforms to microtiter plate dimensional standards. Alternatively, the microfluidic cartridge 100 may be any appropriate size. In a specific application, the microfluidic cartridge 100 can be used to facilitate a PCR procedure for analysis of a sample containing nucleic acids.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at FIG. 1C.  <p>FIG. 1C</p> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at 3:33-52 (“Each sample-port-reagent port pair 113 of an embodiment of the top layer 110 comprises a sample port 114 and a reagent port 115. The sample port 114 functions to receive a volume of a sample fluid potentially containing the nucleic acids of interest for delivery of the volume of fluid to a portion of a fluidic pathway 165 coupled to the sample port-reagent port pair 113. In a specific embodiment, the volume of a sample fluid is a biological sample with magnetic beads for nucleic acid isolation; however, the volume of fluid comprising a sample fluid may alternatively be any appropriate fluid containing a sample with nucleic acids. Preferably, each sample port 114 is isolated from all other sample ports, in order to prevent cross-contamination between samples of nucleic acids being analyzed. Additionally, each sample port 114 is preferably of an appropriate geometric size and shape to accommodate a standard-size pipette tip used to deliver the volume of a sample fluid without leaking. Alternatively, all or a portion of the sample ports 114 are configured to be coupled to fluid conduits or tubing that deliver the volume of a sample fluid.”) U.S. Patent No. 9,403,165 at 4:43-62 (“Preferably, the fluid port 118 is located along an edge of the microfluidic cartridge 100, which functions to increase accessibility to the fluid port by a system delivering fluids to the fluid port 118. In a specific embodiment, as shown in FIG. 1A, the fluid port is

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		<p>located approximately midway along an edge of the microfluidic cartridge 100, different from the edge along which the set of sample port-reagent port pairs 112 is located. Alternatively, the fluid port 118 may not be located along an edge of the microfluidic cartridge 100. Additionally, the fluid port 118 is preferably configured to be coupled to a syringe pump for fluid delivery; however, the fluid port 118 may alternatively configured to couple to any appropriate system for fluid delivery. Preferably, the wash fluid is a wash buffer for washing bound nucleic acid samples (i.e. nucleic acids bound to magnetic beads), the release fluid is a reagent for releasing bound nucleic acids samples from the magnetic beads, and the gas is pressurized air for moving fluids and demarcating separate reagents. Alternatively, the wash fluid, release fluid, and gas may be any appropriate liquids or gases used to carry out a molecular diagnostic procedure.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,403,165 at 4:63-5:16 (“The heating region 195 of the top layer 110 functions to accommodate and position a heating element relative to elements of the microfluidic cartridge 100. The heating element preferably heats a defined volume of fluid and the magnetic beads, which has traveled through the microfluidic cartridge 100, according to a specific molecular diagnostic procedure protocol (e.g. PCR protocol), and is preferably an element external to the microfluidic cartridge 100; alternatively, the heating element may be integrated with the microfluidic cartridge and/or comprise a thermally conductive element integrated into the microfluidic cartridge 100. The heating region 195 is preferably a recessed fixed region of the top layer 110, downstream of the sample port-reagent port pairs 112, as shown in FIGS. 1A and 1B. Alternatively, the heating region may not be fixed and/or recessed, such that the heating region 195 sweeps across the top layer 110 of the microfluidic cartridge 100 as the heating element is moved. The microfluidic cartridge 100 may altogether omit the heating region 195 of the top layer 110, in alternative embodiments using alternative processes (e.g. chemical methods) for releasing nucleic acids from nucleic acid-bound magnetic beads.”) • U.S. Patent No. 9,403,165 at 12:38-58 (“The magnet housing region 150 of the microfluidic cartridge 100 functions to provide access to and/or house at least one magnet 152 providing a magnetic field 156 for purification and isolation of nucleic acids. Preferably, the magnet housing region 150 is defined by the film layer and the intermediate substrate, such that the film layer and the intermediate substrate form the boundaries of the magnet housing region 150. In an embodiment of the microfluidic cartridge 100 comprising a bottom layer 170, the magnet housing region 150 may further be defined by the bottom layer 170, such that the bottom layer partially forms a boundary of the magnet housing region 150. The magnet housing region 150 is preferably a rectangular prism-shaped void in the microfluidic cartridge 150, and accessible only through one side of the microfluidic cartridge 100, as shown in

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		<p>FIG. 1B. Preferably, the magnet housing region 150 can be reversibly passed over a magnet 152 to house the magnet 152, and retracted to remove the magnet 152 from the magnet housing region 150; however, the magnet 152 may alternatively be irreversibly fixed within the magnet housing region 150 once the magnet 152 enters the magnet housing region 150.”)</p> <ul style="list-style-type: none"> <p>U.S. Patent No. 9,403,165 at 12:59-13:21 (“Preferably, the magnet housing region 150 is bounded on at least two sides by the waste chamber 130, and positioned near the middle of the microfluidic cartridge 100, such that a fluidic pathway 165 passing through the magnetic field 156 passes through the magnetic field 156 at least at one point along an intermediate portion of the fluidic pathway 165. Preferably, the magnet housing region 150 also substantially spans at least one dimension of the microfluidic cartridge, such that multiple fluidic pathways 165 of the microfluidic cartridge 100 cross the same magnet housing region 150, magnet 152, and/or magnetic field 156. Alternatively, the magnet housing region 150 may be configured such that a magnet within the magnet housing region 150 provides a magnetic field spanning all fluidic pathways 165 of the microfluidic cartridge in their entirety. In alternative embodiments, the microfluidic cartridge may comprise more than one magnet housing region 150, a magnet housing region 150 may be configured to receive and/or house more than one magnet 152, and/or may not be positioned near the middle of the microfluidic cartridge 100. In yet another alternative embodiment, the magnet housing region 150 may permanently house a magnet 152, such that microfluidic cartridge comprises a magnet 152, integrated with the intermediate substrate 120. In embodiments where the magnet 152 is retractable from the microfluidic cartridge 100, the magnet 152 may be a permanent magnet or an electromagnet. In embodiments where the magnet 152 is configured to be integrated with the microfluidic cartridge 100, the magnet 152 is preferably a permanent magnet, which provides a stronger magnetic field per unit volume.”)</p> <p>U.S. Patent No. 9,403,165 at 13:40-51 (“Furthermore, at least one fluidic pathway 165 in the set of fluidic pathways 160 is preferably configured to be occluded upon deformation of the elastomeric layer 140, configured to transfer a waste fluid to the waste chamber 30, comprises a capture segment 166 passing through the heating region 195 and a magnetic field 156, and is configured to pass through the vent region 190 upstream of a detection chamber 117. Alternative embodiments may omit preferred elements of the embodiment of the fluidic pathway 165 described above, such as a vent region 190 or a heating region 195, or add additional elements to the embodiment of the fluidic pathway 165 described above.”)</p> <p>U.S. Patent No. 9,403,165 at 14:39-56 (“As shown in FIGS. 1C, 6C, 7 and 9, a fluidic pathway 165 of the set of fluidic pathways 160 is branched and preferably comprises an initial segment 174 fluidically coupled to a fluid channel 119 coupled to a fluid port 118, a sample segment 175 coupled to a sample port</p>

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		<p>114, a reagent segment 176 coupled to a reagent port 115, a capture segment 166 passing through at least one of the heating region 195 and a magnetic field 156, a vent segment 177 configured to pass through the vent region 190, a segment running to a detection chamber 163, a segment running away from the detection chamber 164, and at least one waste segment 178, 179 configured to transfer a waste fluid to a waste chamber 130. Individual segments of the fluidic pathway 165 are preferably configured to pass through at least one occlusion position of the set of occlusion positions 141, to controllably direct fluid flow through portions of the fluidic pathway 165. A fluidic pathway 165 may also further comprise an end vent 199, which functions to prevent any fluid from escaping the microfluidic channel.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,403,165 at 14:57-15:10 (“The initial segment 174 of the fluidic pathway 165 functions to deliver common liquids and/or gases from a fluid port 118 through at least a portion of the fluidic pathway 165, the sample segment 175 functions to deliver a volume of a sample fluid (e.g. sample comprising nucleic acids bound to magnetic beads) to a portion of the fluidic pathway 165, and the reagent segment 176 functions to deliver a volume of fluid comprising a reagent to a portion of the fluidic pathway 165. The capture segment 166 functions to facilitate isolation and purification of nucleic acids from the volume of the sample fluid, and may be s-shaped and/or progressively narrowing, to increase the efficiency and/or effectiveness of isolation and purification. Alternatively, the capture segment 166 may altogether be replaced by a substantially straight portion 166 or any other geometric shape or configuration that functions to facilitate isolation and purification of nucleic acids from the volume of the sample fluid. The capture segment 166 of the fluidic pathway 165 preferably has an aspect ratio less than one, which functions to facilitate capture of magnetic particles, but may alternatively have an aspect ratio that is not less than one.”) • U.S. Patent No. 9,403,165 at 15:22-51 (“A first embodiment, as shown in FIG. 1C, of a fluidic pathway 165 preferably comprises an initial segment 174 fluidically coupled to a fluid channel 119 coupled to a shared fluid port 118, a sample segment 175 coupled to a sample port 114 and to the initial segment 174, and an s-shaped capture segment 166, configured to pass through the heating region 195 and a magnetic field 156, coupled to the initial segment 174 and the sample segment 175. In a variation of the first embodiment, the s-shaped capture segment 166 may comprise an initial wide arc 166 to provide a greater surface area for magnetic bead capture. In another variation of the first embodiment, the capture segment 166 may alternatively be a progressively narrowing s-shaped capture segment 166. The first embodiment of the fluidic pathway 165 also comprises a reagent segment 176 coupled to a reagent port 115 and to the capture segment 166, a vent segment 177 coupled to the reagent segment 176 and configured to pass through the vent region 190, a segment running to a detection chamber 163 from the

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		<p>vent region 190, a winding segment running away from the detection chamber 164, and an end vent 199 coupled to the segment running away from the detection chamber 164. The first embodiment of the fluidic pathway 165 also comprises a first waste segment 178 configured to couple the initial segment 174 to the waste chamber 130, and a second waste segment 179 configured to couple the capture segment 166 to the waste chamber 130. The first waste segment 178 preferably functions to allow evacuation of excess release fluids from a fluidic pathway 165, for precise metering of the amount of release reagents used in a molecular diagnostic procedure using a low volume of sample.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,403,165 at 16:7-23 (“The occlusion positions of the set of occlusion positions 141 of the first embodiment are preferably located such that occluding subsets of the set of occlusion positions 141 defines unique truncated fluidic pathways to controllably direct fluid flow. For example, as shown in FIG. 1D, occluding the fluidic pathway 165 at the first, third, fourth, and sixth occlusion positions 142, 144, 145, 147 forms a truncated pathway by which a volume of a sample fluid, comprising nucleic acids bound to magnetic beads and delivered into the sample port 114, may flow past the second occlusion positions 143 into the capture segment 166 for isolation and purification of nucleic acids using the heating region 195 and the magnetic field 156. Nucleic acids bound to magnetic beads may thus be trapped within the capture segment 166 by the magnetic field 156, while other substances in the volume of sample fluid may pass into the waste chamber 130 by passing the fifth occlusion position 146.”) • U.S. Patent No. 9,403,165 16:58-17:5 (“As shown in FIG. 1H, the first and the fourth occlusion positions 142, 145 may then be occluded to form a sixth truncated pathway sealing the volume of release solution, with the captured magnetic beads bound to nucleic acids, within the capture segment 166. The volume of the remaining release solution is therefore substantially defined by the microchannel volume between junctions in the fluidic pathway 165 near the fourth and sixth occlusion positions 145, 147, and may be any small volume but in a specific variation is precisely metered to be 23+/-1 microliters. Release solution may be sealed within capture segments of other fluidic pathways using a similar process. A heater may then be provided at the sixth truncated pathway, inducing a pH shift within the sixth truncated pathway to unbind nucleic acids from the magnetic beads.”) • U.S. Patent No. 9,403,165 at 18:40-65 (“The occlusion positions of the set of occlusion positions 141’ of the second embodiment are preferably located such that occluding of subsets of the set of occlusion positions 141’ defines unique truncated fluidic pathways to controllably direct fluid flow. For example, occluding the fluidic pathway 165’ at the first, fourth, sixth, tenth, and eleventh occlusion positions 142’, 145’, 147’, 158’, 159’ forms a truncated pathway by which a volume of a sample fluid, comprising nucleic acids bound to magnetic beads and delivered into the sample port 114, may flow into the

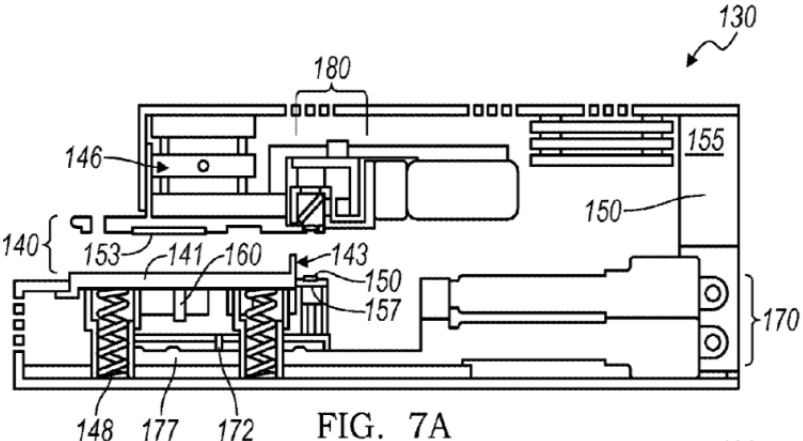
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		<p>capture segment 166' for isolation and purification of nucleic acids using the heating region 195 and the magnetic field 156. Nucleic acids bound to magnetic beads may thus be trapped within the capture segment 166' by the magnetic field 156, while other substances in the volume of sample fluid may pass into the waste chamber 130 by passing the fifth occlusion position 146'. Following this subset of occlusion positions, the occlusion at the first occlusion position 142' may be reversed, and the fluidic pathway 165' may be occluded at the second occlusion position 143' to form a second truncated pathway by which a wash fluid may be delivered through the fluid port 118, into the capture segment 166' (thus washing the trapped magnetic beads), and into the waste chamber 130 by passing the fifth occlusion position 146'. A volume of air may then be pumped through the fluid port 118 to flush any remaining wash solution into the waste chamber 130.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,403,165 at 19:10-25 (“Thereafter, occluding the fluidic pathway 165' at the tenth occlusion position 158', reversing the occlusion at the fourth occlusion position 145' (defining a fourth truncated pathway), and delivering air through the fluid port 118 pushes any remaining release buffer from the fluidic pathway 118 into the waste chamber 130, thereby ensuring that excess release buffer is not later exposed to nucleic acids bound to the magnetic beads (at this point, the nucleic acids are not substantially released from the magnetic beads because heat has not been added). Thereafter, the fluidic pathway 165' is occluded at the first and fourth occlusion positions 142', 145', defining a fifth truncated pathway comprising the capture segment 166', and the magnetic beads are heated to an appropriate temperature and time (e.g., 60 degrees for 5 minutes) within the heating region 195 to release the nucleic acids from the magnetic beads and into the release buffer.”) • U.S. Patent No. 9,403,165 at 20:62-21:16 (“The first channel type 171 is preferably used over a majority of a fluidic pathway 165, and preferably in portions near a vent region 190, in a capture segment 166 configured to pass through a magnetic field 156, and in a segment leading to a Detection chamber 163. Preferably, an embodiment of the first channel type 171, comprising a wide channel with little depth is used in regions configured to pass through a magnetic field 156, such that particles in the regions are driven closer to the magnetic field source. The second channel type 172 is preferably used near a vent region 190 of a fluidic pathway 165, and preferably in portions of a fluidic pathway 165 leading to and away from a detection chamber 163, 164 (to constrict fluid flow into the Detection chamber 117). The third channel type 173 is preferably used in a portion of a fluidic pathway 165 near a normally open position 42 of the set of occlusion positions 141. Transitions between different channel types 171, 172, 173 may be abrupt, or alternatively, may be gradual, as shown in FIG. 8B. The first, second, and third channel types 171, 172, 173 may also alternatively be used in any appropriate portion of a fluidic

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		<p>pathway 165. Example embodiments of channel types for segments of a fluidic pathway are shown in FIG. 8C.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at 21:17-32 (“Multiple fluidic pathways may be configured to pass through a single heating region 195 of the microfluidic cartridge 100, a single vent region 190 of the microfluidic cartridge 100, and/or a magnetic field 156 produced by a magnet 152 housed within a single magnet housing region 150. Preferably all fluidic pathways of the set of fluidic pathways 160 are configured to pass through a single heating region 195 of the microfluidic cartridge 100, a single vent region 190 of the microfluidic cartridge 100, and a magnetic field 156 produced by a magnet 152 housed within a single magnet housing region 150; however, alternative embodiments of the set of fluidic pathways 160 of the microfluidic cartridge may comprise different configurations wherein fluidic pathways of the set of fluidic pathways 160 do not share a single heating region 195, a single vent region 190, and/or a magnetic field 156.”) U.S. Patent No. 9,403,165 at 22:42-55 (“The specific embodiment of the microfluidic cartridge 100 comprises a top layer 110 including a set of twelve sample port-reagent port pairs 112, a set of twelve Detection chambers 116, a shared fluid port 118, a heating region 195, and a vent region 190, an intermediate substrate 120, coupled to the top layer 110 and partially separated from the top layer 110 by a film layer 125, configured to form a waste chamber 130, an elastomeric layer 140 partially situated on the intermediate substrate 120; a magnet housing region 150 accessible by a magnet 152 providing a magnetic field 156; a bottom layer 170 coupled to the intermediate substrate 120 and configured to seal the waste chamber, and a set of fluidic pathways 160, formed by at least a portion of the top layer 110, a portion of the film layer 125, and a portion of the elastomeric layer 140.”) U.S. Patent No. 9,403,165 at 24:39-49 (“The fluidic pathways 165 of the specific embodiment are, in their default condition, open at all occlusion positions, aside from the fourth, seventh, and eighth, occlusion positions 145, 148, 149, as shown in FIG. 1C. Furthermore, the s-shaped capture segment 166 of a fluidic pathway of the specific embodiment is configured to have a volume capacity of 22 ~LL, have a width of 5 .5 mm, and weave back and forth over a magnetic field 156, by crossing the magnet housing region 150. The depth of the s-shaped capture segment 166 is 0.4 mm for the 1.6 mm wide channels and 0.475 for the 0.5 mm narrower channel.”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample,

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		<p>thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • Claim 7. The system of claim 1, wherein a retracted configuration of the actuator allows the magnet to retract from the magnet receiving slot. • Claim 8. The system of claim 1, wherein the magnet is configured to provide a magnetic field spanning at least three fluidic pathways configured to facilitate isolation and extraction of three nucleic acid volumes. • Claim 9. The system of claim 1, wherein the magnet is at least one of an electromagnet and a permanent magnet. • Claim 12. The system of claim 1, wherein the molecular diagnostic module further comprises a molecular diagnostic module heater configured to heat at least one magnetic bead-sample. • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the

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		<p>cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • Claim 23. A system for processing and detecting nucleic acids, comprising: a molecular diagnostic module, configured to process a set of biological samples combined with magnetic beads and separate a set of nucleic acid volumes from the set of biological samples combined with magnetic beads, wherein the molecular diagnostic module comprises an actuator configured to displace a cartridge, a set of pins, and at least one cam contacting the set of pins, wherein an extension or retraction of the actuator moves the cartridge, and a displacement of a subset of the set of pins defines a set of pathways in the cartridge, each configured to receive a biological sample combined with magnetic beads of the set of biological samples combined with magnetic beads. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) • U.S. Patent No. 9,050,594 at 2:49-58 (“As shown in FIGS. 1A-1B and 7A, an embodiment of a system 100 for processing and detecting nucleic acids comprises: a capture plate 110 configured to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119; a molecular diagnostic module 130 comprising a microfluidic cartridge receiving module 140, heating and cooling

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		<p>subsystem 150, a magnet 160, a valve actuation subsystem 170, an optical subsystem 180; and an assay strip 190 configured to facilitate mixing of molecular diagnostic reagents with a nucleic acid volume.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 3:20-33 (“The liquid handling system 250 then aspirates substantially all of each sample of the set of lysed biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate no [sic], and dispenses the set of magnetic bead samples into a microfluidic cartridge 210, aligned within a cartridge receiving module 140 of a molecular diagnostic module 130, and configured to be manipulated by the molecular diagnostic module 130. A heating and cooling subsystem 150, a magnet 160, and a valve actuation subsystem 170 of the molecular diagnostic module 130 then facilitate separation of a set of nucleic acids from the magnetic bead-samples, as the liquid handling system 250 dispenses wash solutions, release solutions, and/or air at appropriate stages.”) • U.S. Patent No. 9,050,594 at 4:45-49 (“Additionally, the magnetic beads may be treated to be positively charged. However, the magnetic beads may alternatively be any appropriate magnetic beads (e.g. magnetic, paramagnetic [sic], or superparamagnetic) configured to facilitate biomagnetic separation.”) • U.S. Patent No. 9,050,594 at 7:24-30 (“As shown in FIGS. 6A and 6B, an embodiment of the molecular diagnostic module 130 of the system 100 includes a cartridge receiving module 140, a heating and cooling subsystem 150, a magnet 160, a valve actuation subsystem 170, and an optical subsystem 180, and functions to manipulate a microfluidic cartridge 210 for processing of a biological sample containing nucleic acids.”) • U.S. Patent No. 9,050,594 at 7:63-8:6 (“As shown in FIGS. 7A-7C, the cartridge platform 141 is preferably configured to receive a microfluidic cartridge 210 along a cartridge loading guiderail 142 until it reaches a cartridge stop 143, and be vertically displaced by the linear actuator 146, which places a biasing force against the set of springs 148 coupled to the cartridge platform 141. The magnet receiving slot 144 and the set of valve actuation slots 145 provide access, by a magnet 160 and a valve actuation subsystem 170, to the microfluidic cartridge 210, as the microfluidic cartridge is vertically displaced by the linear actuator 146.”) • U.S. Patent No. 9,050,594 at FIG. 7A

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		 <p style="text-align: center;">FIG. 7A</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 8:7-12 (“The cartridge platform 141 includes a cartridge loading guiderail 142, a cartridge stop 143, a magnet receiving slot 144, and a set of valve actuation slots 145, and functions to receive and align a microfluidic cartridge 210, while providing access to the microfluidic cartridge 210 by a magnet 160 and a valve actuation subsystem 170.”) U.S. Patent No. 9,050,594 at 8:36-59 (“The embodiment of the cartridge platform 141 shown in FIG. 8 also includes a set of valve actuation slots 145, oriented perpendicular to the parallel cartridge loading guiderails 142 and configured to provide access to a valve actuation subsystem 170, and a magnet receiving slot 144 located among the set of valve actuation slots 145. Preferably, the magnet receiving slot 144 and the set of valve actuation slots 145 substantially span a long dimension of the cartridge platform 141, as shown in FIG. 8, and are configured to correspond to locations on a microfluidic cartridge 210 requiring a magnetic field and/or valving to enable processing of a biological sample and nucleic acid detection once the microfluidic cartridge 210 has been aligned within the molecular diagnostic module 130. Thus, alternative configurations of the magnet receiving slot 144 and the set of valve actuation slots 145 may accommodate other cartridges with alternative regions requiring magnetic fields and/or valving to enable other protocols. In one alternative embodiment, the magnet receiving slot 144 and the set of valve actuation slots may comprise one continuous void of the cartridge platform 141, such that the cartridge platform 141 supports a microfluidic cartridge 210 along the periphery of the microfluidic cartridge 210, but forms a continuous void under a majority of the footprint of the microfluidic cartridge 210.”)

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		<ul style="list-style-type: none"> <p>U.S. Patent No. 9,050,594 at 8:60-9:32 (“The linear actuator 146 functions to linearly displace a microfluidic cartridge 210 resting on the cartridge platform 141, in order to compress the microfluidic cartridge 210 and position the microfluidic cartridge 210 between a cartridge heater 153 and an optical subsystem 180 on one side of the microfluidic cartridge 210, and a magnet 160 and detection chamber heaters 157 on another side of the microfluidic cartridge 210. The linear actuator 146 also functions to provide a sufficient counterforce to the valve actuation subsystem 170 such that a microfluidic cartridge 210 within the molecular diagnostic module 130 remains properly situation upon manipulation by the valve actuation subsystem 170. The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210. In the orientation of the molecular diagnostic module 130 shown in FIGS. 7B and 7B [sic], the linear actuator 146 is preferably coupled to a portion of the heating and cooling subsystem 150 a portion of the optical subsystem 180, and the nozzle 149, and vertically displaces the cartridge heater 153, the optical subsystem 180, and the nozzle 149 to position the cartridge heater 153, 180 and the nozzle 149 over the microfluidic cartridge 210. The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR). Preferably, the linear actuator 146 is a scissor jack actuator configured to apply substantially uniform pressure over all occlusion positions of a microfluidic cartridge 210 aligned within the molecular diagnostic module 130, and to operate in at least two configurations. In a retracted configuration 146 a, as shown in FIG. 9A, the scissor jack actuator has not linearly displaced the cartridge platform 141, and in an extended configuration 146 b, as shown in FIG. 9B, the scissor jack actuator has linearly displaced the microfluidic cartridge 210 to position the microfluidic cartridge 210 between the subsystems 153, and 180, and the magnet 160 and detection chamber heaters 157.”)</p> <p>U.S. Patent No. 9,050,594 at 9:42-55 (“As shown in FIGS. 7B, 7C, and 8, a set of springs 148 is coupled to the cartridge platform 141 and functions to provide a counteracting force against the linear actuator 146 as the linear actuator 146 displaces a microfluidic cartridge 210 resting on the cartridge platform 141. The set of springs 148 thus allows the cartridge platform 141 to return to a position that allows the microfluidic cartridge 210 to be loaded and unloaded from the molecular diagnostic module 130 when the linear actuator 146 is in a retracted configuration 146 b, as shown in FIG. 7B. Preferably, in the orientation shown in FIG. 7B, the set of springs 148 is located at peripheral regions of the bottom side of the cartridge platform 141, such that the set of springs 148 does not interfere with the magnet or the</p>

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		<p>valve actuation subsystem 170.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 10:5-26 (“Similarly, the nozzle 149, the heating and cooling subsystem 150, the cartridge heater 153, and the magnet 160 are preferably coupled to springs, such that springs are positioned between elements 149, 150, 153, and 160, and substrates that elements 149, 150, 153, and 160 are mounted to. Alternatively an elastomeric material is preferably positioned between elements 149, 150, 153, and 160, and substrates that elements 149, 150, 153, and 160 are mounted to. The springs and/or elastomeric material function to provide proper functioning and alignment of subsystems of the molecular diagnostic module 130 as the linear actuator 146 is extended or retracted, contributing to reliability and a reduction in stack up tolerance risk. The springs and/or elastomeric material further function to allow more pressure to be applied to occlusion positions of a microfluidic cartridge 210 aligned within the molecular diagnostic module 130, and an appropriate pressure to be applied to elements 149, 150, 153 and 160 of the molecular diagnostic module 130. Thus, proper contact is maintained between elements 149, 150, 153, and 160, and a microfluidic cartridge 210 being manipulated by the molecular diagnostic module. These elements are described in further detail below.”) • U.S. Patent No. 9,050,594 at 10:49-65 (“The cartridge heater 153 functions to transfer heat to a heating region 224 of a microfluidic cartridge 210, for inducing a pH shift to release bound nucleic acids from magnetic beads within the heating region 224. The cartridge heater 153 is preferably a plate-shaped heater configured to transfer heat to the microfluidic cartridge 210 only from one side of the cartridge heater 153, such that heat flows through one face of the plate-shaped heater to the microfluidic cartridge 210. In a specific example, the cartridge heater 153 is a silicon wafer etched to be conductive and form a resistance heater. In the preferred variation, the cartridge heater 153 is either flip-chip bonded (i.e., soldered to back side of a circuit board), or wire bonded to a circuit board, and then coupled using linear bearings and springs to a plate coupled to the linear actuator 146. The preferred variation allows independent control of 12 independent channels, corresponding to 12 different pathways for sample processing.”) • U.S. Patent No. 9,050,594 at 12:64-13:25 (“The magnet 160 of the molecular diagnostic module 130 functions to provide a magnetic field for isolation and extraction of nucleic acids bound to magnetic beads within a microfluidic cartridge 210, aligned within the molecular diagnostic module 130. Preferably, the magnet 160 is fixed within the molecular diagnostic module 130, such that the extended configuration 146 b of the linear actuator 146 allows the magnet 160 to pass through the magnet receiving slot 144 of the cartridge receiving module 140 and into a magnet housing region 218 of the microfluidic cartridge 210. In an example, as shown in FIGS. 7A-7C, the magnet 160 is a rectangular prism-shaped

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		<p>magnet 160 fixed under the cartridge platform 141, and configured to pass through the cartridge platform 141, into a magnet housing region 218 located under the heating region 224 of the microfluidic cartridge 210. Preferably, the magnet 160 is one of two or three magnets lined up in parallel, such that each of the fluidic pathways of a microfluidic cartridge housing the magnets is exposed to two or three times as much magnetic flux, and two to threes [sic] times as many opportunities to capture magnetic beads. Alternatively, the magnet 160 is a single magnet configured to expose a set of fluidic pathways to a magnetic field. Preferably, the magnet 160 or group of multiple magnets is coupled to a magnet holder within the molecular diagnostic module 130. Additionally, the magnet holder is preferably composed of an insulating material, such that the magnet holder does not interfere with proper functioning of the cartridge heater 153. Alternatively, the magnet holder may not be composed of an insulating material.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 13:26-50 (“In one variation, the magnet 160 or group of multiple magnets comprises a permanent magnet, composed of a magnetized material (e.g., a ferromagnet) providing a substantially fixed magnetic field. In an alternative variation, the magnet 160 or group of multiple magnets comprises an electromagnet configured to provide a modifiable magnetic field, such that the intensity of the magnetic field can be adjusted, the polarity of the magnetic field can be reversed, and the magnetic field can be substantially removed upon removal of a current flowing within the electromagnet. Preferably, the magnet 160 or group of magnets is also fixed relative to the molecular diagnostic module 130; however, the magnet 160 or group of magnets may alternatively be configured to translate vertically (in the orientation shown in FIG. 7B), such that the magnet 160 or group of magnets can extend into and retract from the magnet receiving slot 144 of the cartridge platform 141 and the magnet housing region 218 of the microfluidic cartridge 210. Additionally, the magnet 160 or group of magnets preferably rides on linear bearings and springs (or an elastomeric material) to ensure proper contact with a microfluidic cartridge in an extended configuration 146 b of the linear actuator 146, in a manner that allows most of force from the linear actuator 146 to translate to full occlusion of a subset of the set of occlusion positions (i.e., without leakage).”) • U.S. Patent No. 9,050,594 at 12:64-13:1 (“The magnet 160 of the molecular diagnostic module 130 functions to provide a magnetic field for isolation and extraction of nucleic acids bound to magnetic beads within a microfluidic cartridge 210, aligned within the molecular diagnostic module 130.”) • U.S. Patent No. 9,050,594 at 13:51-54 (“Alternative configurations and/or compositions of the magnet 160 may also be appropriate in facilitating isolation and extraction of nucleic acids bound to magnetic beads within the microfluidic cartridge 210.”)

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		<ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 19:28-43 (“As described above, alternative embodiments of the molecular diagnostic module 130 and alternative variations of subsystems and elements of the molecular diagnostic module 130 may be configured to process a biological sample containing nucleic acids, isolate nucleic acids from the biological sample, and detect nucleic acids. An example of an alternative embodiment of a molecular diagnostic module 130, as shown in FIG. 13, includes a cartridge receiving module 140', a heating and cooling subsystem 150', a magnet 160', a valve actuation subsystem 170', and an optical subsystem 180', and functions to manipulate an alternative microfluidic cartridge 210' for processing of biological samples containing nucleic acids. Other alternative embodiments of the molecular diagnostic module 130" may be configured to receive alternative microfluidic cartridges 210", for processing of biological samples containing nucleic acids.”) U.S. Patent No. 9,050,594 at 22:29-60 (“The microfluidic cartridge 210 functions to receive a set of magnetic bead-samples, facilitate separation of nucleic acids from the set of magnetic bead-samples, receive a set of nucleic acid-reagent samples, and facilitate analysis of nucleic acids from the set of nucleic acid-reagent samples. In one embodiment, the microfluidic cartridge 210 comprises a top layer 211 including a set of sample port-reagent port pairs 212 and a set of detection chambers 213; an intermediate substrate 214, coupled to the top layer 211 and partially separated from the top layer 211 by a film layer 215, configured to form a waste chamber 216; an elastomeric layer 217 partially situated on the intermediate substrate 214; a magnet housing region 218 accessible by a magnet 160 providing a magnetic field; and a set of fluidic pathways 219, each formed by at least a portion of the top layer 211, a portion of the film layer 215, and a portion of the elastomeric layer 217. In the embodiment, the microfluidic cartridge 10 further comprises a bottom layer 221 coupled to the intermediate substrate 214 and configured to seal the waste chamber 216. Furthermore, in the embodiment, the top layer 211 of the microfluidic cartridge 210 further comprises a shared fluid port 222, a vent region 223, and a heating region 224, such that each fluidic pathway 220 in the set of fluidic pathways 219 is fluidically coupled to a sample port-reagent port pair 224, the shared fluid port 222, the waste chamber 216, and a detection chamber 225, comprises a turnabout portion 226 configured to pass through the heating region 224 and the magnetic field, and is configured to pass through the vent region 223 upstream of the detection chamber 225. Each fluidic pathway 220 thus functions to receive and facilitate processing of a sample fluid containing nucleic acids as it passes through different portions of the fluidic pathway 220.”) U.S. Patent No. 9,050,594 at 22:61-23:5 (“The microfluidic cartridge 210 is preferably configured to be received and manipulated by the molecular diagnostic module 130, such that the cartridge receiving module 140 of the molecular diagnostic module 130 receives and aligns the microfluidic cartridge 210

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		<p>within the molecular diagnostic module 130, the heating and cooling subsystem 150 of the molecular diagnostic module 130 is configured to transfer heat to the heating region 224 of the microfluidic cartridge 210, and the magnet 160 of the molecular diagnostic module 130 is configured to be received by the magnet housing region 218 of the microfluidic cartridge 210 to provide a magnetic field for separation of nucleic acids.")</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 23:28-58 ("The liquid handling system 250 of the system 100 includes a liquid handling arm 255 and a syringe pump 265, as shown in FIGS. 14A-14C and functions to deliver biological samples, reagents, and gases to elements of the system 100. As described in Section 1, an embodiment of the liquid handling system 250 is configured to aspirate a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), dispense the set of biological samples into a capture plate no to be lysed and combined with magnetic beads by a capture plate module 120, aspirate the set of biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate 110, and dispense the set of magnetic bead-samples into microfluidic cartridge 210 located in a molecular diagnostic module 130. The embodiment of the liquid handling system 100 is further configured to facilitate separation of a set of nucleic acids from the magnetic bead-samples, by dispensing a wash solution, a release solution, and/or air into the molecular diagnostic module 130, by the nozzle 149 coupled to the linear actuator 146, at appropriate stages, aspirate the set of nucleic acids from the molecular diagnostic module 130, combine the set of nucleic acids with a set of molecular diagnostic reagents using an assay strip 190, and dispense the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the molecular diagnostic module 130 for further processing and analysis. [Other embodiments of the liquid handling system 250 may be configured to perform alternative molecular diagnostic assay protocols and/or dispense and aspirate alternative fluids into and from other elements supporting a molecular diagnostic protocol.]") • U.S. Patent No. 9,050,594 at 27:2-13 ("An embodiment of a method 400 for processing and detecting nucleic acids from a set of biological samples comprises: combining each biological sample of the set of biological samples with a quantity of magnetic beads to produce a set of magnetic bead-sample mixtures S410; heating the set of magnetic bead-sample mixtures to produce a set of nucleic acid-magnetic bead samples S420; transferring each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways S430; producing a set of nucleic acid volumes from the set of nucleic acid-magnetic bead samples S440;") • U.S. Patent No. 9,050,594 at 28:53-29:4 ("Step S430 recites transferring each nucleic acid-magnetic bead

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		<p>sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways, and functions to isolate each of the set of nucleic acid-magnetic bead samples within separate pathways for further processing. Preferably, all nucleic acid-magnetic bead samples in the set of nucleic acid-magnetic bead samples are transferred simultaneously to the set of fluidic pathways, but alternatively, each nucleic acid-magnetic bead sample in the set of magnetic bead-samples may be transferred to a corresponding fluidic pathway independently of the other nucleic acid-magnetic bead samples. In addition, preferably the entire volume, or substantially all of the volume, of the nucleic acid-magnetic bead sample is transferred to the set of fluidic pathways, without magnetically isolating magnetic beads and removing supernatant fluids prior to transferring each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 29:5-11 (“Step S430 may further comprise occluding at least one fluidic pathway of the set of fluidic pathways at a subset of a set of occlusion positions S432, which functions to define at least one truncated fluidic pathway. Preferably, Step S432 comprises defining at least one truncated fluidic pathway passing through at least one of a heating region and a magnetic field;”) • U.S. Patent No. 9,050,594 at 29:14-26 (“In a specific example of Step S430, the multichannel liquid handling subsystem of Step S410 transfers a set of nucleic acid-magnetic bead samples to a set of fluidic pathways of a microfluidic cartridge aligned within a molecular diagnostic module, wherein the microfluidic cartridge comprises an elastomeric layer in contact with the set of fluidic pathways. Manipulation of the elastomeric layer at a subset of a set of occlusion positions by a valve actuation subsystem of the molecular diagnostic module defines a set of truncated fluidic pathways crossing a heating region and a magnetic field, such that each nucleic acid-magnetic bead sample in the set of nucleic acid-magnetic bead samples is isolated within a truncated fluidic pathway of the set of truncated fluidic pathways.”) • U.S. Patent No. 9,050,594 at 29:27-50 (“Step S440 recites producing a set of nucleic acid volumes from the set of nucleic acid-magnetic bead samples, and functions to separate nucleic acid volumes from the set of nucleic acid-magnetic bead samples. Step S440 preferably reduces a concentration of unwanted matter from the set of biological samples being processed, to an acceptable level; however, Step S440 may alternatively entirely remove substantially all unwanted substances from the set of biological samples being processed. Step S440 preferably includes providing a magnetic field S441, such that each fluidic pathway in the set of fluidic pathways is configured to cross the magnetic field. Preferably, the set of nucleic acid-magnetic bead samples is captured and isolated within portions of the set of fluidic

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		<p>pathways crossing the magnetic field. Step S440 may further comprise providing a heater configured to span a heating region of the set of fluidic pathways S442, but may alternatively comprise providing multiple heaters or altogether omit providing a heater. In embodiments wherein multiple heaters are provided, each heater is preferably independent to allow independent control of heating time and temperature for each sample. Step S442 functions to provide a heater, which, in combination with a release solution that provides a pH shift, facilitate a rapid and efficient unbinding of the nucleic acids from magnetic beads.")</p>
1(g)	a heater assembly configured to heat at least one process chamber of the plurality of process chambers in the first module	<p>In the accused system, the first module comprises, a heater assembly configured to heat at least one process chamber of the plurality of process chambers in the first module.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to "VIDEO NeuMoDx™ WORKFLOW" hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • "Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber." <i>Id.</i> at 2:28-2:39. • <i>Id.</i> at 2:28 (showing lysate in the s-channel).

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		<div data-bbox="661 228 1627 771" data-label="Image"> </div> <ul style="list-style-type: none"> <p>“A precise volume of air is then applied to remove any remaining liquid into the waste chamber. NeuMoDx wash solution is pumped via the fluid port into the microfluidic cartridge to remove all unbound material, followed by another volume of air to remove excess wash solution. High pH NeuMoDx release reagent is dispensed into the s-channel to cover the beads, and heat is applied to the denaturation process, resulting in released nucleic acid or eluate.” <i>Id.</i> at 2:39-3:12.</p> <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> <p>Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a</p>

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		<p>set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 3. The method of claim 1, wherein receiving the binding moiety solution, comprising the set of affinity moiety-coated microparticles, comprises receiving a set of magnetic microparticles covalently bonded to a set of affinity moiety molecules, and wherein contacting the binding moiety solution with the biological sample comprises aspirating the binding moiety solution along with the biological sample from the process chamber and dispensing the binding moiety solution with the biological sample to the process chamber. • Claim 4. The method of claim 3, wherein incubating the moiety-sample mixture comprises heating the moiety-sample solution to a temperature in the range of 25-95° C. for 5-60 minutes, thus simultaneously lysing the biological sample and facilitating binding of nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles. • Patent No. 9,382,532 at 3:43-47 (“The process chamber or any other device can also be configured to enable another set of conditions (e.g., suitably high pH, suitably low salt concentration, and/or suitably high temperature) that facilitate release of bound nucleic acids.”) • Patent No. 9,382,532 at 9:31-62 (“ In some variations, Step S160 can further comprise Step S161, which recites heating the moiety-bound nucleic acid volume. Step S161 functions to provide additional environmental conditions that facilitate release of the nucleic acid sample from the microparticles, and can further function to mitigate effects of proteolytic enzymes that are used in Steps S110, S120, and/or S130 or that may be released from the biological sample containing the nucleic acid. Preferably, an elevated temperature in combination with an elevated pH resulting from the elution solution provides the enhanced conditions to facilitate the release of the nucleic acid sample. Furthermore, an elevated temperature (e.g., elevating a sample eluted at room temperature to 85 C) can function to minimize protease enzyme activity in the eluted nucleic acid and thereby improve the robustness of the detection of the target nucleic acid sample during processing in variations of Step S110;

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		<p>however, the method 100 can alternatively omit Step S161 in applications wherein heating the moiety-bound nucleic acid volume is undesirable and/or unnecessary. Furthermore, variations of Step S161 can comprise heating at higher temperatures for shorter time periods, or heating at lower temperatures for longer time periods. In an example of Step S161, heating comprises elevating the temperature of the moiety-bound nucleic acid volume to 80-85 C, for 3 minutes, and in another example, heating comprises elevating the temperature of the moiety-bound nucleic acid volume to 50-70 C, for 3-10 minutes. In other examples, the elevation temperature can be maintained at a desired set-point for as low as 1 minute or as high as 30 minutes. Further, elution conditions may be optimized to ensure that the bound nucleic acid is only eluted in the presence of the high pH solution at the elevated temperature for a specified amount of time.”)</p> <ul style="list-style-type: none"> • Patent No. 9,382,532 at 9:63-10:13 (“In a specific example of Steps S160 and S161, a system (such as the one described in U.S. patent application Ser. No. 13/766,359, entitled "System and Method for Processing and Detecting Nucleic Acids") can be used to deliver the elution solution into a fluidic pathway of a cartridge (such as the one described in U.S. patent application Ser. No. 13/765,996, entitled "Microfluidic Cartridge for Processing and Detecting Nucleic Acids"). In the variation of the specific example, the microparticles of the moiety-bound nucleic acid volume can be retained by a magnetic field within a portion of the fluidic pathway upon occlusion of the fluidic pathway at a suitable set of occlusion positions, and the elution solution can be delivered through the portion of the fluidic pathway enable release of the nucleic acid sample from the microparticle. Additionally, a heating element of the system can be moved proximal to the portion of the fluidic pathway with the elution solution and the microparticles to further enhance release of the nucleic acid sample.”) • Patent No. 9,382,532 at 10:46-57 (“In specific examples, however, Step S165 can comprise any combination of: not washing the moiety-bound nucleic acid volume, passively washing the moiety-bound nucleic acid volume, not removing a wash solution from the moiety-bound nucleic acid volume, washing the moiety-bound nucleic acid volume with a Tris solution (e.g., 1 mM Tris solution), eluting the nucleic acid sample at room temperature, eluting the nucleic acid sample at 99 C, eluting the nucleic acid sample at 55 C, and not resuspending moiety-bound microparticles in a release buffer, any combination of which can affect amplification of the nucleic acids or the process control.”) • Patent No. 9,382,532 at 13:42-60 (“A first example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, cerebrospinal fluid (CSF) as a representative biological sample, and Enterovirus (EV) viral particles as the model target. In the first example, 200 µL of CSF was spiked with 2 uL of EV viral particle lysate and then mixed with 500 µL of RNA Collection Buffer 1

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		<p>(CBR-1) and 300 µL of nuclease-free water in examples of Steps S110 and S120. As a comparison, a similar amount of EV particle lysate was spiked into a 1 mL solution comprised of 500 µL of CBR-1 buffer and 500 µL of nuclease-free water and processed simultaneously. In an example of Step S130, RNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 60 C. Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2×) with 500 µL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”)</p> <ul style="list-style-type: none"> • Patent No. 9,382,532 at 14:5-23 (“A second example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, M4 transport medium containing a nasal swab (donor) as a representative biological sample, and Enterovirus (EV) viral particles as the model target. In the second example, 500 µL of M4 transport media containing a nasal swab (donor) was spiked with 2 µL of either a 10–2 dilution (high) or a 10µ4 (low) dilution of EV RNA (purified from 200 µL viral particle lysate and eluted in 20 µL total volume) and then mixed with 500 µL of RNA Collection Buffer 1 (CBR-1) and 0.4 mg of Proteinase K in examples of Steps S110 and S120. RNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 60 C in an example of Step S130. Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2×) with 250 µL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) • Patent No. 9,382,532 at 14:41-59 (“A third example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, Universal Transport Medium (UTM) containing a nasal swab (donor) as a representative biological sample, and Enterovirus (EV) viral particles as the model target. In the third example, 500 µL of UTM transport media containing a nasal swab (donor) was spiked with 2 µL of a 10–4 dilution of EV RNA (purified from 200 µL viral particle lysate and eluted in 20 µL total volume) and then mixed with 500 µL of RNA Collection Buffer 1 (CBR-1) and 0.6 mg of Proteinase K in examples of Steps S110 and S120. RNA was allowed to bind to the PAA affinity particles coated onto magnetic microparticles for 10 minutes at 60 C in an example of Step S130. Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2×) with 100 µL or 250 µL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”)

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		<ul style="list-style-type: none"> Patent No. 9,382,532 at 15:8-24 (“A fourth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, M4 transport medium containing nasal swab (donor) as a representative biological sample, and Enterovirus (EV) viral particles as the model target. In the fourth example, 500 μL of M4 transport media containing a nasal swab (donor) was spiked with 2 μL of ten-fold dilutions of EV viral particle lysate and then mixed with 500 μL of RNA Collection Buffer 1 (CBR-1) and 0.4 mg of Proteinase K in examples of Steps S110 and S120. RNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 60 C in an example of Step S130. Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2\times) with 100 μL of WSH-1 solution in an example of Step S150, and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) Patent No. 9,382,532 at 15:58-6:12 (“A fifth example of the method 100 comprises using DABAM affinity moieties coated onto magnetic microparticles, Human Urine (donor), Human Plasma and Buccal Swab (donor) as representative biological sample matrices, and Group B Streptococcus (GBS) DNA (ATCC, Virginia) as the model target. In the fifth example, 500 μL of Urine or Plasma was spiked with 10 pg of GBS DNA and then mixed with 500 μL of DNA Collection Buffer 2 (CBD-2) in examples of Steps S110 and S120. Alternately, a buccal swab was added to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg Proteinase K and then spiked with 10 pg of GBS DNA in other examples of Steps S110 and S120. DNA was allowed to bind to the DABAM affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature or 60 C depending on matrix used in examples of Step S130. Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 μL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-1 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) Patent No. 9,382,532 at 16:29-44 (“A sixth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, Human Urine (donor) as a representative biological sample, and Group B Streptococcus (GBS) DNA as the model target. In the sixth example, 500 μL of Urine (obtained from donor) was spiked with mpg of GBS DNA and then mixed with 500 μL of DNA Collection Buffer 2 (CBD-2) in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature in an example of Step S130. Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 μL of WSH-1 solution in an example of Step

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		<p>S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”)</p> <ul style="list-style-type: none"> • Patent No. 9,382,532 at 16:61-16:10 (“A seventh example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, Human Plasma (donor, obtained from Bioreclamation, Inc.) as a representative biological sample, and Group B Streptococcus (GBS) DNA as the model target. In the seventh example, 500 µL of Plasma was spiked with mpg of GBS DNA and then mixed with 500 µL of DNA Collection Buffer 2 (CBD-2) in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature in an example of Step S130. Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 µL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the magnetic microparticles to 85 C for 3 minutes in an example of Step S160.”) • Patent No. 9,382,532 at 17:27-43 (“An eighth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, simulated swab specimens as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target. In the eighth example, a buccal swab (obtained from a donor) was added to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg Proteinase K and then spiked with 10 pg of GBS DNA in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37 C in an example of Step S130. Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 µL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) • Patent No. 9,382,532 at 17:60-18:14 (“A ninth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, simulated swab transport media specimens as representative biological samples and Group B Streptococcus (GBS) DNA as the model target. In the ninth example 500 µL of M4 Transport Media (M4) or Universal Transport Media (UTM) containing a buccal swab (obtained from a donor) was spiked with 10 pg of GBS DNA and then mixed with 500 µL of DNA Collection Buffer 3 (CBD-3) and 0.4 mg of Proteinase K in examples of Steps S110 and S120. For comparison, “Dry Swab” samples were prepared by adding a buccal swab to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg Proteinase K and then spiked with 10 pg of GBS DNA. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37 C in an example of Step S130. Upon removal of the unbound supernatant in an example of Step S140, the

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		<p>magnetic microparticles with bound DNA were washed with 500 μL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”)</p> <ul style="list-style-type: none"> Patent No. 9,382,532 at 18:31-47 (“A tenth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, whole blood as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target. In the tenth example, 100 μL whole blood (donor, obtained from Bioreclamation, Inc.) was added to 1 mL of DNA Collection Buffer 1 (CBD-1) containing 0.4 mg Proteinase K and then spiked with 10 pg of GBS DNA in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 37 C in an example of Step S130. Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed twice with 500 μL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) Patent No. 9,382,532 at 19:12-27 (“An eleventh example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, Urine (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target. In the eleventh example, 500 μL of urine (obtained from a donor) was spiked with ten-fold serial dilutions of GBS DNA from 1 ng to 10 fg and then mixed with 500 μL of DNA Collection Buffer 2 (CBR-2) in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature in an example of Step S130. Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 μL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) Patent No. 9,382,532 at 19:46-61 (“A twelfth example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, plasma (donor) as a representative biological sample, and Group B Streptococcus (GBS) DNA as the model target. In the twelfth example, 500 μL of plasma was spiked with ten-fold serial dilutions of GBS DNA from 1 ng to 10 fg and then mixed with 500 μL of DNA Collection Buffer 2 (CBR-2) in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature in an example of Step S130. Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 μL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3

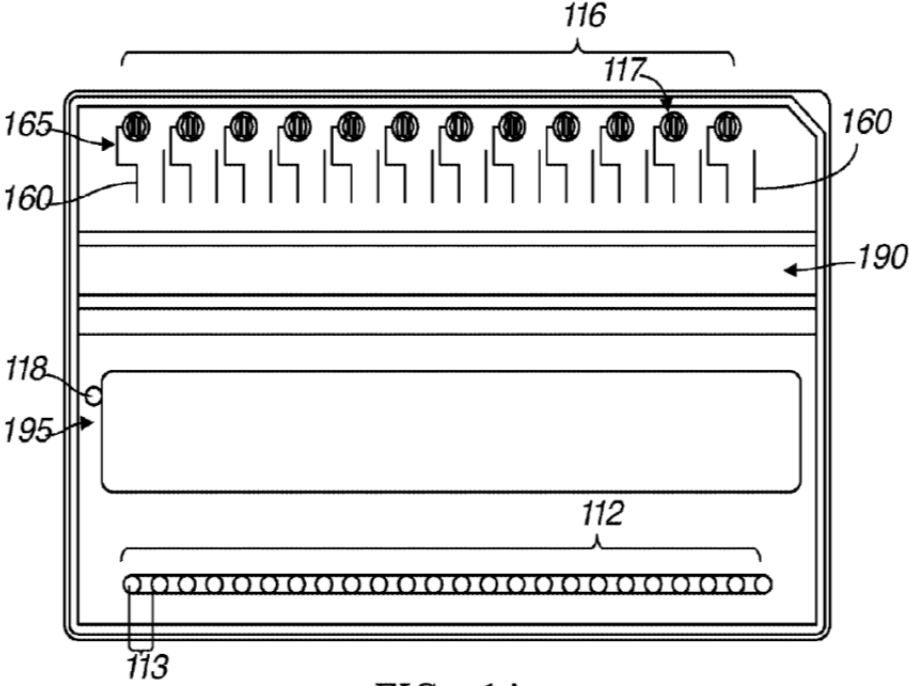
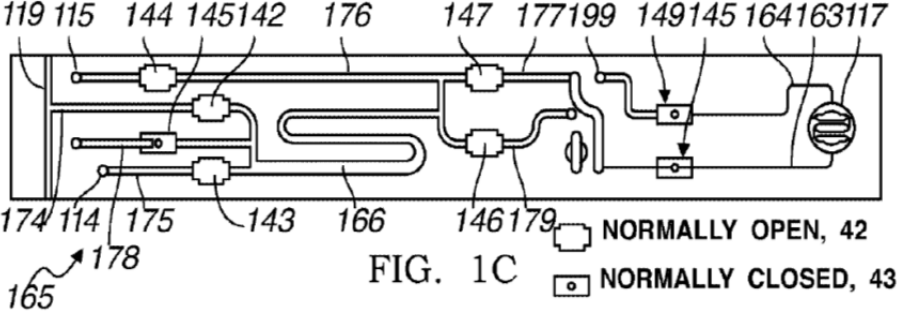
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		<p>minutes in an example of Step S160.”)</p> <ul style="list-style-type: none"> Patent No. 9,382,532 at 20:7-23 (“A thirteenth example of the method 100, demonstrating the effect of binding time, comprises using PAA affinity moieties coated onto magnetic microparticles, Human Plasma (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA (ATCC, Virginia) as the model target. In the thirteenth example, 500 µL of Plasma was spiked with mpg of GBS DNA and then mixed with 500 µL of DNA Collection Buffer 2 (CBD-2) in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 0, 2, 5, or 10 minutes at room temperature in examples of Step S130. Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 µL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) Patent No. 9,382,532 at 20:33-50 (“A fourteenth example of the method 100, demonstrating the effect of binding temperature, comprises using PAA affinity moieties coated onto magnetic microparticles, Human Plasma (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA (ATCC, Virginia) as the model target. In the fourteenth example, 500 µL of Plasma was spiked with mpg of GBS DNA and then mixed with 500 µL of DNA Collection Buffer 2 (CBD-2) in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature, 37 C, 45 C, or 60 C in examples of Steps S130. Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 µL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) Patent No. 9,382,532 at 21:23-39 (“A fifteenth example of the method 100, demonstrating the effect of binding temperature, comprises using PAA affinity moieties coated onto magnetic microparticles, Urine (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target. In the fifteenth example, 500 µL of Urine (obtained from a donor) was spiked with mpg of GBS DNA and then mixed with 500 µL of DNA Collection Buffer 2 (CBD-2) in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature, 37 C, 45 C, or 60 C in examples of Step S130. Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 µL of WSH-1 solution in an example of Step S150, and the captured DNA was eluted from the affinity matrix by using ELU-2 and heating the microparticles to 85 C for 3 minutes in an

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		<p>example of Step S160.”)</p> <ul style="list-style-type: none"> Patent No. 9,382,532 at 21:59-22:8 (“A sixteenth example of the method 100, demonstrating the use of two different elution solutions, comprises using PAA affinity moieties coated onto magnetic microparticles, Human Urine (donor) as a representative biological sample and Group B Streptococcus (GBS) DNA as the model target. In the sixteenth example, 500 μL of Urine (obtained from donor) was spiked with mpg of GBS DNA and then mixed with 500 μL of DNA Collection Buffer 2 (CBD-2) in examples of Steps S110 and S120. DNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at room temperature in an example of Step S130. Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound DNA were washed with 500 μL of WSH-1 solution in an example of Step S150 and the captured DNA was eluted from the affinity matrix by using ELU-2 or ELU-3 and heating the microparticles to 85 C for 3 minutes in an example of Step S160.”) Patent No. 9,382,532 at 22:31-49 (“A seventeenth example of the method 100, demonstrating the use of nucleic acid isolation reagents for total nucleic acid (TNA) extraction, comprises using PAA affinity moieties coated onto magnetic microparticles, M4 transport media as a representative biological sample, and Enterovirus (EV) viral particles as the model RNA target and Group B Streptococcus DNA as model DNA target. In the seventeenth example, 500 μL of M4 was spiked with ten-fold serial dilutions of 1 μL of EV viral particle lysate and 1 μL of GBS DNA and then mixed with 500 μL of RNA Collection Buffer 3 (CBR-3) in examples of Steps S110 and S120. RNA and DNA were allowed to bind to the PAA affinity moieties for 10 minutes at 37 C in an example of Step S130. Upon removal of the unbound supernatant in an example of Step S140, the PAA affinity moieties coated onto magnetic microparticles were washed twice (2\times) with 500 μL of WSH-1 solution in an example of Step S150, and then the captured RNA and DNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) Patent No. 9,382,532 at 24:1-12 (“A first illustration of the eighteenth example, as shown in FIG. 22A, of a fluidic pathway 165 preferably comprises an initial segment 174 fluidically coupled to a fluid channel 119 coupled to a shared fluid port 118, a sample segment 175 coupled to a sample port 114 and to the initial segment 174, and an s-shaped capture segment 166, configured to pass through the heating region 195 and a magnetic field 156, coupled to the initial segment 17 4 and the sample segment 175. In an alternative illustration of the eighteenth example, the s-shaped capture segment 166 may comprise an initial wide arc 166 to provide a greater surface area for magnetic bead capture.”) Patent No. 9,382,532 at 24:53-65 (“The occlusion positions of the set of occlusion positions 141 of the

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		<p>first illustration are preferably located such that occluding subsets of the set of occlusion positions 141 defines unique truncated fluidic pathways to controllably direct fluid flow. For example, as shown in FIG. 22B, occluding the fluidic pathway 165 at the first, third, fourth, and sixth occlusion positions 142, 144, 145, 147 forms a truncated pathway by which a volume of a sample fluid, comprising nucleic acids bound to magnetic beads and delivered into the sample port 114, may flow past the second occlusion positions 143 into the capture segment 166 for isolation and purification of nucleic acids using the heating region 195 and the magnetic field 156.”)</p> <ul style="list-style-type: none"> • Patent No. 9,382,532 at 25:30-50 (“Thereafter, the occlusion at the fourth occlusion position 145 maybe reversed, creating a fifth truncated pathway, and release solution within the fluidic pathway 165 may be metered by pumping air through the fluid port 118, which functions to push a portion of the release solution into the waste chamber 130. A volume of release solution will still be maintained within the capture segment 166 at this stage. The first and the fourth occlusion positions 142, 145 may then be occluded to form a sixth truncated pathway sealing the volume of release solution, with the captured magnetic beads bound to nucleic acids, within the capture segment 166. The volume of the remaining release solution is therefore substantially defined by the microchannel volume between junctions in the fluidic pathway 165 near the fourth and sixth occlusion positions 145, 147, and maybe any small volume but in a specific variation is precisely metered to be 23+/-1 microliters. Release solution may be sealed within capture segments of other fluidic pathways using a similar process. A heater may then be provided at the sixth truncated pathway, inducing a pH shift within the sixth truncated pathway to unbind nucleic acids from the magnetic beads.”) • Patent No. 9,382,532 at 26:28-34 (“A second illustration of the eighteenth example, of a fluidic pathway 165' preferably comprises an initial segment 174 fluidically coupled to a fluid channel 119' coupled to a shared fluid port 118', a sample segment 175' coupled to a sample port 114' and to the initial segment 174', and a capture segment 166', configured to pass through the heating region 195 and a magnetic field 156, coupled to the initial segment 174'.”) • Patent No. 9,382,532 at 27:17-42 (“The occlusion positions of the set of occlusion positions 141' of the second illustration are preferably located such that occluding of subsets of the set of occlusion positions 141' defines unique truncated fluidic pathways to controllably direct fluid flow. For example, occluding the fluidic pathway 165' at the first, fourth, sixth, tenth, and eleventh occlusion positions 142', 145', 147', 158', 159' forms a truncated pathway by which a volume of a sample fluid, comprising nucleic acids bound to magnetic beads and delivered into the sample 25 port 114, may flow into the capture segment 166' for isolation and purification of nucleic acids using the heating region 195 and the magnetic field

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		<p>156. Nucleic acids bound to magnetic beads may thus be trapped within the capture segment 166' by the magnetic field 156, while other substances in the volume of sample fluid may pass into the waste chamber 130 by passing the fifth occlusion position 146'. Following this subset of occlusion positions, the occlusion at the first occlusion position 142' may be reversed, and the fluidic pathway 165' may be occluded at the second occlusion position 143' to form a second truncated pathway by which a wash fluid may be delivered through the fluid port 118, into the capture segment 166' (thus washing the trapped magnetic beads), and into the waste chamber 130 by passing the fifth occlusion position 146'. A volume of air may then be pumped through the fluid port 118 to flush any remaining wash solution into the waste chamber 130.”)</p> <ul style="list-style-type: none"> Patent No. 9,382,532 at 27:43-28:2 (“Thereafter, in the second illustration, the fluidic pathway 165' may be occluded at the fifth occlusion position 146' and the occlusion at the tenth occlusion position 158' may be reversed, closing access to the waste chamber 130 and opening access to the end vent segment 197'. A release solution may then be delivered through the fluid port 118, into the capture segment 166', and to the end vent segment 197'. The volume of the release solution is therefore defined by the microchannel volume between the fourth and tenth occlusion positions 145', 158', and maybe any small volume but in a specific variation is precisely metered to be 15 microliters. Thereafter, occluding the fluidic pathway 165' at the tenth occlusion position 158', reversing the occlusion at the fourth occlusion position 145' (defining a fourth truncated pathway), and delivering air through the fluid port 118 pushes any remaining release buffer from the fluidic pathway 118 into the waste chamber 130, thereby ensuring that excess release buffer is not later exposed to nucleic acids bound to the magnetic beads (at this point, the nucleic acids are not substantially released from the magnetic beads because heat has not been added). Thereafter, the fluidic pathway 165' is occluded at the first and fourth occlusion positions 142', 145', defining a fifth truncated pathway comprising the capture segment 166', and the magnetic beads are heated to an appropriate temperature and time (e.g., 60 degrees for 5 minutes) within the heating region 195 to release the nucleic acids from the magnetic beads and into the release buffer.”) <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate

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		<p>and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position of the fluidic pathway, by way of the void of the corrugated surface, the fluidic pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber.</p> <ul style="list-style-type: none"> • Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate. • Claim 10. The cartridge of claim 8, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the second detection chamber, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port. • Claim 11. The cartridge of claim 10, further comprising 1) a heating region defined as a recessed region of the first layer that is parallel to the set of voids of the corrugated surface, and 2) a vent region, such that the first fluidic pathway is configured to cross the heating region and to pass through the vent region upstream of the first detection chamber, and the second fluidic pathway is configured to cross the heating region and to pass through the vent region upstream of the second detection chamber. • U.S. Patent No. 9,403,165 at 3:27-32 (“As shown in FIGS. 1B and 1C, the top layer 110 preferably comprises a set of sample port-reagent port pairs 112, a fluid port 118, a vent region 190, a heating region 195 crossing a capture segment 166 of a fluidic pathway 165, and a set of detection chambers 116.”) • U.S. Patent No. 9,403,165 at 1A.

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		 <p style="text-align: center;">FIG. 1A</p> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at FIG. 1C .  <p style="text-align: center;">FIG. 1C</p> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at 13:40-51 (“Furthermore, at least one fluidic pathway 165 in the set of fluidic pathways 160 is preferably configured to be occluded upon deformation of the elastomeric layer 140,

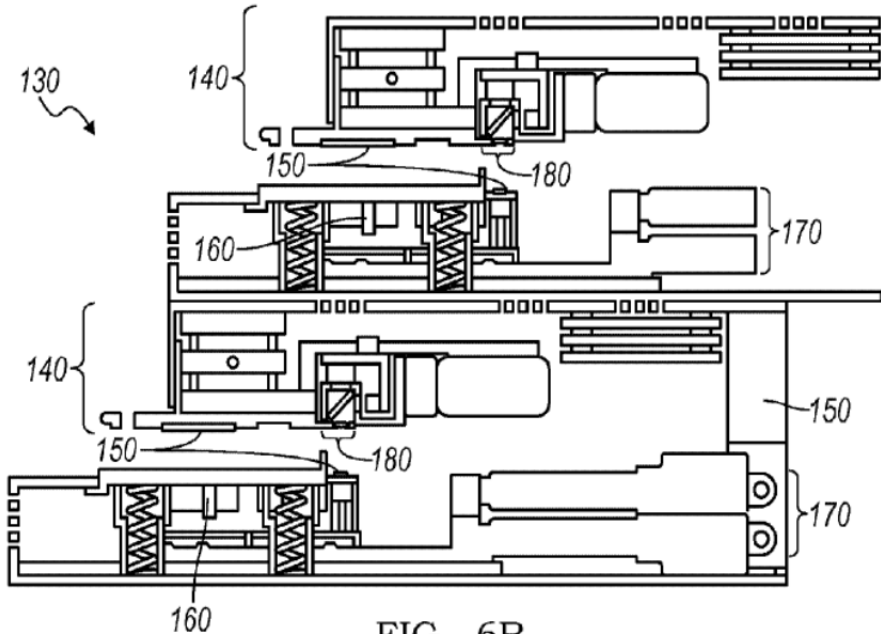
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		<p>configured to transfer a waste fluid to the waste chamber 30, comprises a capture segment 166 passing through the heating region 195 and a magnetic field 156, and is configured to pass through the vent region 190 upstream of a detection chamber 117. Alternative embodiments may omit preferred elements of the embodiment of the fluidic pathway 165 described above, such as a vent region 190 or a heating region 195, or add additional elements to the embodiment of the fluidic pathway 165 described above.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,403,165 at 14:39-56 (“As shown in FIGS. 1C, 6C, 7 and 9, a fluidic pathway 165 of the set of fluidic pathways 160 is branched and preferably comprises an initial segment 174 fluidically coupled to a fluid channel 119 coupled to a fluid port 118, a sample segment 175 coupled to a sample port 114, a reagent segment 176 coupled to a reagent port 115, a capture segment 166 passing through at least one of the heating region 195 and a magnetic field 156, a vent segment 177 configured to pass through the vent region 190, a segment running to a detection chamber 163, a segment running away from the detection chamber 164, and at least one waste segment 178, 179 configured to transfer a waste fluid to a waste chamber 130. Individual segments of the fluidic pathway 165 are preferably configured to pass through at least one occlusion position of the set of occlusion positions 141, to controllably direct fluid flow through portions of the fluidic pathway 165. A fluidic pathway 165 may also further comprise an end vent 199, which functions to prevent any fluid from escaping the microfluidic channel.”) • U.S. Patent No. 9,403,165 at 15:22-51 (“A first embodiment, as shown in FIG. 1C, of a fluidic pathway 165 preferably comprises an initial segment 174 fluidically coupled to a fluid channel 119 coupled to a shared fluid port 118, a sample segment 175 coupled to a sample port 114 and to the initial segment 174, and an s-shaped capture segment 166, configured to pass through the heating region 195 and a magnetic field 156, coupled to the initial segment 174 and the sample segment 175. In a variation of the first embodiment, the s-shaped capture segment 166 may comprise an initial wide arc 166 to provide a greater surface area for magnetic bead capture. In another variation of the first embodiment, the capture segment 166 may alternatively be a progressively narrowing s-shaped capture segment 166. The first embodiment of the fluidic pathway 165 also comprises a reagent segment 176 coupled to a reagent port 115 and to the capture segment 166, a vent segment 177 coupled to the reagent segment 176 and configured to pass through the vent region 190, a segment running to a detection chamber 163 from the vent region 190, a winding segment running away from the detection chamber 164, and an end vent 199 coupled to the segment running away from the detection chamber 164. The first embodiment of the fluidic pathway 165 also comprises a first waste segment 178 configured to couple the initial segment 174 to the waste chamber 130, and a second waste segment 179 configured to couple the capture segment 166 to the waste chamber 130. The first waste segment 178 preferably functions to allow evacuation of excess

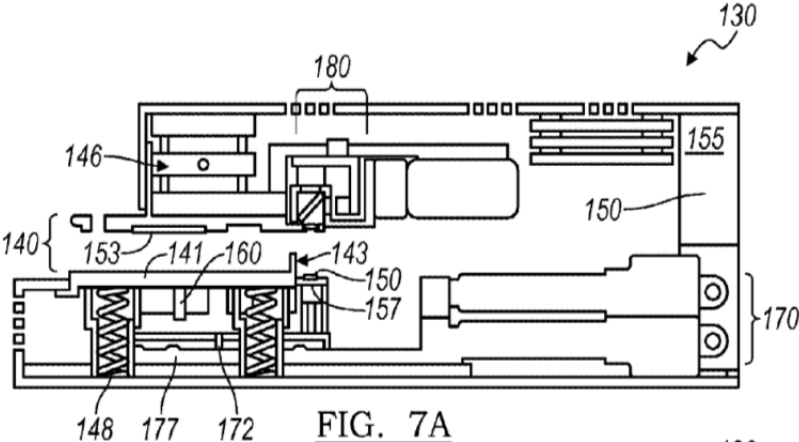
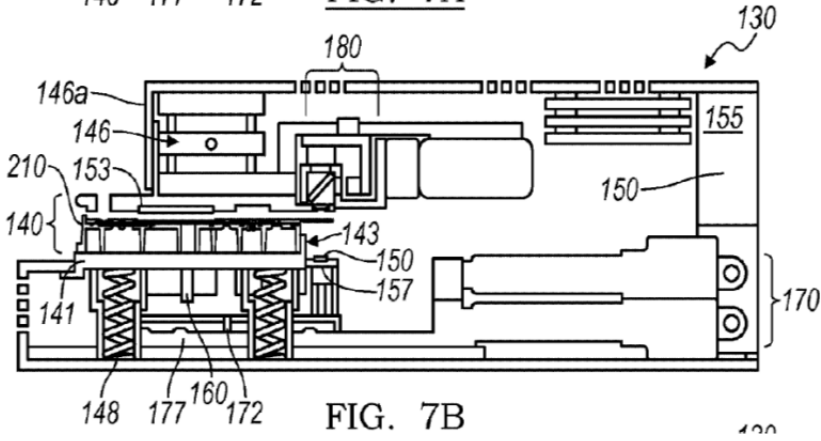
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		<p>release fluids from a fluidic pathway 165, for precise metering of the amount of release reagents used in a molecular diagnostic procedure using a low volume of sample.”)</p> <ul style="list-style-type: none"> <p>U.S. Patent No. 9,403,165 at 16:7-23 (“The occlusion positions of the set of occlusion positions 141 of the first embodiment are preferably located such that occluding subsets of the set of occlusion positions 141 defines unique truncated fluidic pathways to controllably direct fluid flow. For example, as shown in FIG. 1D, occluding the fluidic pathway 165 at the first, third, fourth, and sixth occlusion positions 142, 144, 145, 147 forms a truncated pathway by which a volume of a sample fluid, comprising nucleic acids bound to magnetic beads and delivered into the sample port 114, may flow past the second occlusion positions 143 into the capture segment 166 for isolation and purification of nucleic acids using the heating region 195 and the magnetic field 156. Nucleic acids bound to magnetic beads may thus be trapped within the capture segment 166 by the magnetic field 156, while other substances in the volume of sample fluid may pass into the waste chamber 130 by passing the fifth occlusion position 146.”)</p> <p>U.S. Patent No. 9,403,165 at 16:58-17:5 (“As shown in FIG. 1H, the first and the fourth occlusion positions 142, 145 may then be occluded to form a sixth truncated pathway sealing the volume of release solution, with the captured magnetic beads bound to nucleic acids, within the capture segment 166. The volume of the remaining release solution is therefore substantially defined by the microchannel volume between junctions in the fluidic pathway 165 near the fourth and sixth occlusion positions 145, 147, and may be any small volume but in a specific variation is precisely metered to be 23+/-1 microliters. Release solution may be sealed within capture segments of other fluidic pathways using a similar process. A heater may then be provided at the sixth truncated pathway, inducing a pH shift within the sixth truncated pathway to unbind nucleic acids from the magnetic beads.”)</p> <p>U.S. Patent No. 9,403,165 at 17:51-57 (“A second embodiment, as shown in FIG. 6C, of a fluidic pathway 165' preferably comprises an initial segment 174' fluidically coupled to a fluid channel 119' coupled to a shared fluid port 118', a sample segment 175' coupled to a sample port 114' and to the initial segment 174', and a capture segment 166', configured to pass through the heating region 195 and a magnetic field 156, coupled to the initial segment 174'.”)</p> <p>U.S. Patent No. 9,403,165 at 18:40-65 (“The occlusion positions of the set of occlusion positions 141' of the second embodiment are preferably located such that occluding of subsets of the set of occlusion positions 141' defines unique truncated fluidic pathways to controllably direct fluid flow. For example, occluding the fluidic pathway 165' at the first, fourth, sixth, tenth, and eleventh occlusion positions 142', 145', 147', 158', 159' forms a truncated pathway by which a volume of a sample fluid, comprising nucleic acids bound to magnetic beads and delivered into the sample port 114, may flow into the capture</p>

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		<p>segment 166' for isolation and purification of nucleic acids using the heating region 195 and the magnetic field 156. Nucleic acids bound to magnetic beads may thus be trapped within the capture segment 166' by the magnetic field 156, while other substances in the volume of sample fluid may pass into the waste chamber 130 by passing the fifth occlusion position 146'. Following this subset of occlusion positions, the occlusion at the first occlusion position 142' may be reversed, and the fluidic pathway 165' may be occluded at the second occlusion position 143' to form a second truncated pathway by which a wash fluid may be delivered through the fluid port 118, into the capture segment 166' (thus washing the trapped magnetic beads), and into the waste chamber 130 by passing the fifth occlusion position 146'. A volume of air may then be pumped through the fluid port 118 to flush any remaining wash solution into the waste chamber 130.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,403,165 at 19:10-25 (“Thereafter, occluding the fluidic pathway 165' at the tenth occlusion position 158', reversing the occlusion at the fourth occlusion position 145' (defining a fourth truncated pathway), and delivering air through the fluid port 118 pushes any remaining release buffer from the fluidic pathway 118 into the waste chamber 130, thereby ensuring that excess release buffer is not later exposed to nucleic acids bound to the magnetic beads (at this point, the nucleic acids are not substantially released from the magnetic beads because heat has not been added). Thereafter, the fluidic pathway 165' is occluded at the first and fourth occlusion positions 142', 145', defining a fifth truncated pathway comprising the capture segment 166', and the magnetic beads are heated to an appropriate temperature and time (e.g., 60 degrees for 5 minutes) within the heating region 195 to release the nucleic acids from the magnetic beads and into the release buffer.”) • U.S. Patent No. 9,403,165 at 21:17-32 (“Multiple fluidic pathways may be configured to pass through a single heating region 195 of the microfluidic cartridge 100, a single vent region 190 of the microfluidic cartridge 100, and/or a magnetic field 156 produced by a magnet 152 housed within a single magnet housing region 150. Preferably all fluidic pathways of the set of fluidic pathways 160 are configured to pass through a single heating region 195 of the microfluidic cartridge 100, a single vent region 190 of the microfluidic cartridge 100, and a magnetic field 156 produced by a magnet 152 housed within a single magnet housing region 150; however, alternative embodiments of the set of fluidic pathways 160 of the microfluidic cartridge may comprise different configurations wherein fluidic pathways of the set of fluidic pathways 160 do not share a single heating region 195, a single vent region 190, and/or a magnetic field 156.”) • U.S. Patent No. 9,403,165 at 22:42-55 (“The specific embodiment of the microfluidic cartridge 100 comprises a top layer 110 including a set of twelve sample port-reagent port pairs 112, a set of twelve

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		<p>Detection chambers 116, a shared fluid port 118, a heating region 195, and a vent region 190, an intermediate substrate 120, coupled to the top layer 110 and partially separated from the top layer 110 by a film layer 125, configured to form a waste chamber 130, an elastomeric layer 140 partially situated on the intermediate substrate 120; a magnet housing region 150 accessible by a magnet 152 providing a magnetic field 156; a bottom layer 170 coupled to the intermediate substrate 120 and configured to seal the waste chamber, and a set of fluidic pathways 160, formed by at least a portion of the top layer 110, a portion of the film layer 125, and a portion of the elastomeric layer 140.”)</p> <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 12. The system of claim 1, wherein the molecular diagnostic module further comprises a molecular diagnostic module heater configured to heat at least one magnetic bead-sample. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid

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		<p>handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) • U.S. Patent No. 9,050,594 at 3:20-33 (“The liquid handling system 250 then aspirates substantially all of each sample of the set of lysed biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate no [sic], and dispenses the set of magnetic bead samples into a microfluidic cartridge 210, aligned within a cartridge receiving module 140 of a molecular diagnostic module 130, and configured to be manipulated by the molecular diagnostic module 130. A heating and cooling subsystem 150, a magnet 160, and a valve actuation subsystem 170 of the molecular diagnostic module 130 then facilitate separation of a set of nucleic acids from the magnetic bead-samples, as the liquid handling system 250 dispenses wash solutions, release solutions, and/or air at appropriate stages.”) • U.S. Patent No. 9,050,594 at 7:24-30 (“As shown in FIGS. 6A and 6B, an embodiment of the molecular diagnostic module 130 of the system 100 includes a cartridge receiving module 140, a heating and cooling subsystem 150, a magnet 160, a valve actuation subsystem 170, and an optical subsystem 180, and functions to manipulate a microfluidic cartridge 210 for processing of a biological sample containing nucleic acids.”)

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		<ul style="list-style-type: none"> <li data-bbox="617 238 1150 266">U.S. Patent No. 9,050,594 at FIG. 6B.  <p data-bbox="1045 933 1199 971">FIG. 6B</p> <ul style="list-style-type: none"> <li data-bbox="617 987 2011 1421">U.S. Patent No. 9,050,594 at 8:60-9:15 (“The linear actuator 146 functions to linearly displace a microfluidic cartridge 210 resting on the cartridge platform 141, in order to compress the microfluidic cartridge 210 and position the microfluidic cartridge 210 between a cartridge heater 153 and an optical subsystem 180 on one side of the microfluidic cartridge 210, and a magnet 160 and detection chamber heaters 157 on another side of the microfluidic cartridge 210. The linear actuator 146 also functions to provide a sufficient counterforce to the valve actuation subsystem 170 such that a microfluidic cartridge 210 within the molecular diagnostic module 130 remains properly situation upon manipulation by the valve actuation subsystem 170. The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210. In the orientation of the molecular diagnostic module 130 shown in FIGS. 7B and 7B [sic], the linear actuator 146 is preferably coupled to a portion of the heating and cooling subsystem 150 a portion of the optical subsystem 180, and the nozzle 149, and


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		<p>vertically displaces the cartridge heater 153, the optical subsystem 180, and the nozzle 149 to position the cartridge heater 153, 180 and the nozzle 149 over the microfluidic cartridge 210.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at FIG. 7A  <p style="text-align: center;">FIG. 7A</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at FIG. 7B  <p style="text-align: center;">FIG. 7B</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 10:5-26 (“Similarly, the nozzle 149, the heating and cooling subsystem 150, the cartridge heater 153, and the magnet 160 are preferably coupled to springs, such that springs


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		<p>are positioned between elements 149,150, 153, and 160, and substrates that elements 149, 150, 153, and 160 are mounted to. Alternatively an elastomeric material is preferably positioned between elements 149,150, 153, and 160, and substrates that elements 149, 150, 153, and 160 are mounted to. The springs and/or elastomeric material function to provide proper functioning and alignment of subsystems of the molecular diagnostic module 130 as the linear actuator 146 is extended or retracted, contributing to reliability and a reduction in stack up tolerance risk. The springs and/or elastomeric material further function to allow more pressure to be applied to occlusion positions of a microfluidic cartridge 210 aligned within the molecular diagnostic module 130, and an appropriate pressure to be applied to elements 149, 150, 153 and 160 of the molecular diagnostic module 130. Thus, proper contact is maintained between elements 149, 150, 153, and 160, and a microfluidic cartridge 210 being manipulated by the molecular diagnostic module. These elements are described in further detail below.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 10:29-48 (“The heating and cooling subsystem 150 of the molecular diagnostic module 130 comprises a cartridge heater 153, a fan 155, and a set of detection chamber heaters 157 and functions to controllably heat portions of a microfluidic cartridge 210 for processing of a biological sample containing nucleic acids according to a molecular diagnostic protocol. In the orientation of an embodiment of the molecular diagnostic module 130 shown in FIGS. 7A-7C, the cartridge heater 153 is preferably coupled to the linear actuator 146 of the cartridge receiving module 140 and configured to span a central region of a microfluidic cartridge 210 aligned within the molecular diagnostic module 130, the fan 155 is located at a back wall of the cartridge receiving module 140, and the set of detection chamber heaters 157 is located inferior to a set of detection chambers 213 of the microfluidic cartridge 210. In alternative embodiments of the molecular diagnostic module 130, the heating and cooling subsystem 150 may have any appropriate alternative configuration that provides controlled heating and cooling to a microfluidic cartridge within the molecular diagnostic module 130.”) • U.S. Patent No. 9,050,594 at 10:49-65 (“The cartridge heater 153 functions to transfer heat to a heating region 224 of a microfluidic cartridge 210, for inducing a pH shift to release bound nucleic acids from magnetic beads within the heating region 224. The cartridge heater 153 is preferably a plate-shaped heater configured to transfer heat to the microfluidic cartridge 210 only from one side of the cartridge heater 153, such that heat flows through one face of the plate-shaped heater to the microfluidic cartridge 210. In a specific example, the cartridge heater 153 is a silicon wafer etched to be conductive and form a resistance heater. In the preferred variation, the cartridge heater 153 is either flip-chip bonded (i.e., soldered to back side of a circuit board), or wire bonded to a circuit board, and then

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		<p>coupled using linear bearings and springs to a plate coupled to the linear actuator 146. The preferred variation allows independent control of 12 independent channels, corresponding to 12 different pathways for sample processing.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 11:13-32 (“Preferably, the cartridge heater 153 is configured to linearly translate with the linear actuator 146 of the cartridge receiving module 140, in order to align with a heating region 224 spanning a central portion of a microfluidic cartridge 210 aligned within the molecular diagnostic module 130. In one variation, the cartridge heater 153 is preferably fixed relative to the linear actuator 146 such that (in the orientation shown in FIGS. 7B-7C), the cartridge heater 153 can only move vertically with the linear actuator. In an alternative variation, the cartridge heater 153 may additionally be configured to translate laterally with a horizontal plane (in the orientation shown in FIGS. 7B-7C), such that the cartridge heater 153 can translate in at least two perpendicular coordinate planes. In this alternative variation, the cartridge heater 153 can be configured to sweep across a surface of a microfluidic cartridge 210 aligned within the molecular diagnostic module 130, or to translate in response to motion of the microfluidic cartridge 210, such that the position of the cartridge heater 153 relative to a heating region 224 of the microfluidic cartridge 210 is always fixed.”) • U.S. Patent No. 9,050,594 at 13:6-25 (“In an example, as shown in FIGS. 7A-7C, the magnet 160 is a rectangular prism-shaped magnet 160 fixed under the cartridge platform 141, and configured to pass through the cartridge platform 141, into a magnet housing region 218 located under the heating region 224 of the microfluidic cartridge 210. Preferably, the magnet 160 is one of two or three magnets lined up in parallel, such that each of the fluidic pathways of a microfluidic cartridge housing the magnets is exposed to two or three times as much magnetic flux, and two to three [sic] times as many opportunities to capture magnetic beads. Alternatively, the magnet 160 is a single magnet configured to expose a set of fluidic pathways to a magnetic field. Preferably, the magnet 160 or group of multiple magnets is coupled to a magnet holder within the molecular diagnostic module 130. Additionally, the magnet holder is preferably composed of an insulating material, such that the magnet holder does not interfere with proper functioning of the cartridge heater 153. Alternatively, the magnet holder may not be composed of an insulating material.”) • U.S. Patent No. 9,050,594 at 19:28-43 (“As described above, alternative embodiments of the molecular diagnostic module 130 and alternative variations of subsystems and elements of the molecular diagnostic module 130 may be configured to process a biological sample containing nucleic acids, isolate nucleic acids from the biological sample, and detect nucleic acids. An example of an alternative embodiment of a molecular diagnostic module 130, as shown in FIG. 13, includes a cartridge receiving module 140’, a

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		<p>heating and cooling subsystem 150', a magnet 160', a valve actuation subsystem 170', and an optical subsystem 180', and functions to manipulate an alternative microfluidic cartridge 210' for processing of biological samples containing nucleic acids. Other alternative embodiments of the molecular diagnostic module 130" may be configured to receive alternative microfluidic cartridges 210", for processing of biological samples containing nucleic acids.")</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 22:47-60 ("Furthermore, in the embodiment, the top layer 211 of the microfluidic cartridge 210 further comprises a shared fluid port 222, a vent region 223, and a heating region 224, such that each fluidic pathway 220 in the set of fluidic pathways 219 is fluidically coupled to a sample port-reagent port pair 224, the shared fluid port 222, the waste chamber 216, and a detection chamber 225, comprises a turnabout portion 226 configured to pass through the heating region 224 and the magnetic field, and is configured to pass through the vent region 223 upstream of the detection chamber 225. Each fluidic pathway 220 thus functions to receive and facilitate processing of a sample fluid containing nucleic acids as it passes through different portions of the fluidic pathway 220.") • U.S. Patent No. 9,050,594 at 22:61-23:5 ("The microfluidic cartridge 210 is preferably configured to be received and manipulated by the molecular diagnostic module 130, such that the cartridge receiving module 140 of the molecular diagnostic module 130 receives and aligns the microfluidic cartridge 210 within the molecular diagnostic module 130, the heating and cooling subsystem 150 of the molecular diagnostic module 130 is configured to transfer heat to the heating region 224 of the microfluidic cartridge 210, and the magnet 160 of the molecular diagnostic module 130 is configured to be received by the magnet housing region 218 of the microfluidic cartridge 210 to provide a magnetic field for separation of nucleic acids.") • U.S. Patent No. 9,050,594 at 29:5-13 ("Step S430 may further comprise occluding at least one fluidic pathway of the set of fluidic pathways at a subset of a set of occlusion positions S432, which functions to define at least one truncated fluidic pathway. Preferably, Step S432 comprises defining at least one truncated fluidic pathway passing through at least one of a heating region and a magnetic field; however, Step S432 may alternatively not comprise defining a truncated fluidic pathway passing through at least one of a heating region and a magnetic field.") • U.S. Patent No. 9,050,594 at 29:14-26 ("In a specific example of Step S430, the multichannel liquid handling subsystem of Step S410 transfers a set of nucleic acid-magnetic bead samples to a set of fluidic pathways of a microfluidic cartridge aligned within a molecular diagnostic module, wherein the microfluidic cartridge comprises an elastomeric layer in contact with the set of fluidic pathways. Manipulation of the elastomeric layer at a subset of a set of occlusion positions by a valve actuation

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		<p>subsystem of the molecular diagnostic module defines a set of truncated fluidic pathways crossing a heating region and a magnetic field, such that each nucleic acid-magnetic bead sample in the set of nucleic acid-magnetic bead samples is isolated within a truncated fluidic pathway of the set of truncated fluidic pathways.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 29:27-50 (“Step S440 recites producing a set of nucleic acid volumes from the set of nucleic acid-magnetic bead samples, and functions to separate nucleic acid volumes from the set of nucleic acid-magnetic bead samples. Step S440 preferably reduces a concentration of unwanted matter from the set of biological samples being processed, to an acceptable level; however, Step S440 may alternatively entirely remove substantially all unwanted substances from the set of biological samples being processed. Step S440 preferably includes providing a magnetic field S441, such that each fluidic pathway in the set of fluidic pathways is configured to cross the magnetic field. Preferably, the set of nucleic acid-magnetic bead samples is captured and isolated within portions of the set of fluidic pathways crossing the magnetic field. Step S440 may further comprise providing a heater configured to span a heating region of the set of fluidic pathways S442, but may alternatively comprise providing multiple heaters or altogether omit providing a heater. In embodiments wherein multiple heaters are provided, each heater is preferably independent to allow independent control of heating time and temperature for each sample. Step S442 functions to provide a heater, which, in combination with a release solution that provides a pH shift, facilitate a rapid and efficient unbinding of the nucleic acids from magnetic beads.”) U.S. Patent No. 9,050,594 at 30:6-7 (“The heater provided in Step S442 may be activated after Step S445 to induce a pH shift.”)
1(h)	a second module configured to receive nucleic acids extracted from the plurality of nucleic acid-containing samples,	<p>The accused system comprises a second module configured to receive nucleic acids extracted from the plurality of nucleic acid-containing samples.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “Liquid Handling Processing C: The Test Strip. After piercing the test strip, the liquid handling robot moves to the PCR port or p-port of the microfluidic cartridge, where it aspirates the eluate out of the cartridge into the pipette tip. Once the aspiration step is complete, the eluate is delivered to the appropriate wells in the NeuMoDx test strip, where it is dispensed and aspirated ten times to ensure

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		<p>homogeneous resuspension of the NeuDry PCR reagents. The sample mixes with primers and probes.” <i>Id.</i> at 3:12-3:57.</p> <ul style="list-style-type: none"> <i>Id.</i> at 3:36 (showing the liquid handling robot at the test strip)  <p><i>NeuMoDx Molecular N288 System</i>, http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ TECHNOLOGY” hyperlink at https://player.vimeo.com/video/281470603. (Exhibit 17)</p> <ul style="list-style-type: none"> At 4:17 (showing the liquid dispenser at the microfluidic cartridge)

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		<div data-bbox="564 228 1629 824"></div> <ul style="list-style-type: none">• At 4:29 (showing the liquid dispenser at the reagent strip)

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		 <p data-bbox="569 938 884 971">US9382532 (Exhibit 52)</p> <ul data-bbox="617 980 2011 1414" style="list-style-type: none"> • Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic

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		<p>pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> <p>U.S. Patent No. 9,382,532 at 11:2-23 (“In one variation, the nucleic acid sample eluted from the microparticles can be aspirated (e.g., by a pipette tip or by a fluid handling system) into another process chamber and combined with process reagents for further processing and characterization. In a specific example of this variation, a system (such as the one described in U.S. patent application Ser. No. 13/766,359, entitled "System and Method for Processing and Detecting Nucleic Acids") can be used to aspirate the nucleic acid sample from a fluidic pathway of a cartridge (such as the one described in U.S. patent application Ser. No. 13/765,996, entitled "Microfluidic Cartridge for Processing and Detecting Nucleic Acids"), while the microparticles are immobilized by a magnet. The system can then combine the nucleic acid sample with process reagents (e.g., PCR reagents) in a separate container (e.g., assay plate), and then transfer the nucleic acid sample combined with process reagents to a detection chamber of the fluidic pathway (upon occlusion and/or opening of the fluidic channel at another subset of occlusion positions). The nucleic acid sample combined with process reagents can then be processed within a diagnostic chamber that is coupled to the fluidic pathway.”)</p> <p>Patent No. 9,382,532 at 25:51-26:10 (“Thereafter in the first illustration, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An</p>

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		<p>external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”)</p> <ul style="list-style-type: none"> Patent No. 9,382,532 at 28:324 (“Thereafter, in the second illustration, the occlusions at the first and eleventh occlusion positions 142', 159' are reversed, defining a sixth truncated pathway, the entire released nucleic acid sample (e.g. -15 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent mixture stored off of the microfluidic cartridge 100. During the reconstitution process, the occlusion at the sixth occlusion position 147' may be reversed, thus defining a seventh truncated pathway. Once reconstitution of the molecular diagnostic reagent mixture with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be aspirated through the reagent port 115 through the seventh truncated pathway to the detection chamber 117, completely filling the detection chamber 117, after which the fluidic pathway 165' is be occluded at third, seventh, eighth, and ninth occlusion positions 144', 148', 149', 157' defining an eighth truncated pathway. An external molecular diagnostic system and/or module may then perform additional processes on the volume of fluid within the detection chamber 117.”) <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at 17:6-33 (“Thereafter in the first embodiment, as shown in FIG. H the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 micro liters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic


Claim	Claim Language	Infringement Evidence
		<p>system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at 19:26-46 (“Thereafter, in the second embodiment, the occlusions at the first and eleventh occlusion positions 142', 159' are reversed, defining a sixth truncated pathway, the entire released nucleic acid sample (e.g. -15 micro liters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent mixture stored off of the microfluidic cartridge 100. During the reconstitution process, the occlusion at the sixth occlusion position 147' may be reversed, thus defining a seventh truncated pathway. Once reconstitution of the molecular diagnostic reagent mixture with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be aspirated through the reagent port 115 through the seventh truncated pathway to the detection chamber 117, completely filling the detection chamber 117, after which the fluidic pathway 165' is be occluded at third, seventh, eighth, and ninth occlusion positions 144', 148', 149', 157' defining an eighth truncated pathway. An external molecular diagnostic system and/or module may then perform additional processes on the volume of fluid within the detection chamber 117.”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module. Claim 21. The system of claim 16, wherein the liquid handling system comprises a multichannel


Claim	Claim Language	Infringement Evidence
		<p>pipette head and a syringe pump.</p> <ul style="list-style-type: none"> • Claim 23. A system for processing and detecting nucleic acids, comprising: a molecular diagnostic module, configured to process a set of biological samples combined with magnetic beads and separate a set of nucleic acid volumes from the set of biological samples combined with magnetic beads, wherein the molecular diagnostic module comprises an actuator configured to displace a cartridge, a set of pins, and at least one cam contacting the set of pins, wherein an extension or retraction of the actuator moves the cartridge, and a displacement of a subset of the set of pins defines a set of pathways in the cartridge, each configured to receive a biological sample combined with magnetic beads of the set of biological samples combined with magnetic beads. • Claim 24. The system of claim 23, further comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample, a lysing reagent, and a sample process control, wherein the capture plate facilitates production of at least one biological sample combined with magnetic beads; an assay strip comprising at least one reagent well containing a molecular diagnostic reagent volume configured to be combined with a nucleic acid volume of the set of nucleic acid volumes to produce at least one nucleic acid-reagent mixture; and a liquid handling system configured to transfer at least one biological sample combined with magnetic beads from the capture plate to the molecular diagnostic module, transfer at least one nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer at least one nucleic acid-reagent mixture from the assay strip back to the molecular diagnostic module. • Claim 32. The system of claim 24, wherein the liquid handling system comprises a multichannel pipette head and a syringe pump. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) • U.S. Patent No. 9,050,594 at 2:49-3:1 (“As shown in FIGS. 1A-1B and 7A, an embodiment of a system


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		<p>100 for processing and detecting nucleic acids comprises: a capture plate 110 configured to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119; a molecular diagnostic module 130 comprising a microfluidic cartridge receiving module 140, heating and cooling subsystem 150, a magnet 160, a valve actuation subsystem 170, an optical subsystem 180; and an assay strip 190 configured to facilitate mixing of molecular diagnostic reagents with a nucleic acid volume. Other embodiments of the system 100 may further comprise at least one of a capture plate module 120 configured to support the capture plate 110; a filter 200 and filter holder 205 to facilitate sample preparation; a microfluidic cartridge 210 configured to facilitate sample processing; an assay strip holder 230; an assay strip carrier 240; a liquid handling system 250 configured to facilitate gas and fluid delivery to different elements of the system 100; a processor configured to analyze data resulting from a run of the system 100; and a user interface configured to allow a user to interact with the system 100.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 3:14-46 (“In one example workflow of the system 100, a liquid handling system 250 aspirates a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), and dispenses the set of biological samples into a capture plate 110 to be lysed and combined with magnetic beads (containing a proprietary affinity coating to bind the nucleic acids to the magnetic beads) by a capture plate module 120. The liquid handling system 250 then aspirates substantially all of each sample of the set of lysed biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate no [sic], and dispenses the set of magnetic bead-samples into a microfluidic cartridge 210, aligned within a cartridge receiving module 140 of a molecular diagnostic module 130, and configured to be manipulated by the molecular diagnostic module 130. A heating and cooling subsystem 150, a magnet 160, and a valve actuation subsystem 170 of the molecular diagnostic module 130 then facilitate separation of a set of nucleic acids from the magnetic bead-samples, as the liquid handling system 250 dispenses wash solutions, release solutions, and/or air at appropriate stages. The liquid handling system 250 then aspirates the set of nucleic acids from the microfluidic cartridge 210 contained within the molecular diagnostic module 130, combines the set of nucleic acids with a set of molecular diagnostic reagents using an assay strip 190, and dispenses the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the microfluidic cartridge 210 within the molecular diagnostic module 130. The detection chamber heaters 157, optical subsystem 180 and valve actuation subsystem 170 of the molecular diagnostic module 130 then facilitate analysis of the set of nucleic acid-reagent mixtures by a processor configured to display information on a user interface.”) • U.S. Patent No. 9,050,594 at 23:28-58 (“The liquid handling system 250 of the system 100 includes a

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		<p>liquid handling arm 255 and a syringe pump 265, as shown in FIGS. 14A-14C and functions to deliver biological samples, reagents, and gases to elements of the system 100. As described in Section 1, an embodiment of the liquid handling system 250 is configured to aspirate a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), dispense the set of biological samples into a capture plate no [sic] to be lysed and combined with magnetic beads by a capture plate module 120, aspirate the set of biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate 110, and dispense the set of magnetic bead-samples into microfluidic cartridge 210 located in a molecular diagnostic module 130. The embodiment of the liquid handling system 100 is further configured to facilitate separation of a set of nucleic acids from the magnetic bead-samples, by dispensing a wash solution, a release solution, and/or air into the molecular diagnostic module 130, by the nozzle 149 coupled to the linear actuator 146, at appropriate stages, aspirate the set of nucleic acids from the molecular diagnostic module 130, combine the set of nucleic acids with a set of molecular diagnostic reagents using an assay strip 190, and dispense the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the molecular diagnostic module 130 for further processing and analysis. [Other embodiments of the liquid handling system 250 may be configured to perform alternative molecular diagnostic assay protocols and/or dispense and aspirate alternative fluids into and from other elements supporting a molecular diagnostic protocol.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 30:27-53 (“Step S450 recites combining each nucleic acid volume of the set of nucleic acid volumes with a molecular diagnostic reagent of a set of molecular diagnostic reagents to produce a set of nucleic acid-reagent mixtures, which functions to prepare the set of nucleic acid volumes to be detected. For each nucleic acid volume in the set of nucleic acid volumes, Step S450 preferably comprises aspirating an entire volume of the nucleic acid volume from its corresponding fluidic pathway, and transferring the nucleic acid volume to a well containing a molecular diagnostic reagent. Preferably, all nucleic acid volumes in the set of nucleic acid volumes are aspirated and combined with molecular diagnostic reagents simultaneously using a multichannel fluid delivery system; however, each nucleic acid volume in the set of nucleic acid volumes may alternatively be aspirated and combined with molecular diagnostic reagents independently of the other nucleic acid volumes. The molecular diagnostic reagents preferably comprise reagents configured to analyze the set of nucleic acid volumes for markers of at least one of gonorrhea (GC), Chlamydia (CT), herpes simplex virus (HSV), human immunodeficiency virus (HIV), human respiratory diseases, vaginal diseases, hepatitis C virus (HCV), hepatitis B virus (HBV), trichomonas, group B

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		<p>streptococcus (GBS), factor 2 (FII) gene, and factor five (FV) gene, but may alternatively comprise reagents used to detect any specific nucleic acid sequence.”)</p> <ul style="list-style-type: none"> <p>U.S. Patent No. 9,050,594 at 30:54-31:6 (“In a first variation of Step S450 as shown in FIG. 16A, a nucleic acid volume is aspirated and combined with a molecular diagnostic reagent for a single assay. In the first variation of Step S450, a set of nucleic acid volumes may thus be aspirated simultaneously, and each nucleic acid volume may be transferred to an individual well to be combined with a molecular diagnostic reagent of a set of molecular diagnostic reagents to produce a set of nucleic acid-reagent mixtures. In the first variation of Step S450, all nucleic acid-reagent mixtures in the set of nucleic acid-reagent mixtures may or may not be substantially identical in composition, depending on the homogeneity of the biological samples used in Step S410; however, the first variation of S450 preferably comprises using identical molecular diagnostic reagents, such that identical molecular diagnostic protocols analyzing identical markers may be performed. Thus, the first variation of Step S450 encompasses running multiple identical tests from a stock biological sample (e.g., a multiplex assay), and running identical tests using a set of substantially different biological samples (e.g., from different sources).”)</p> <p>U.S. Patent No. 9,050,594 at 31:7-19 (“In a second variation of Step S450, as shown in FIG. 16B, the set of nucleic acid volumes is aspirated, and each nucleic acid volume in the set of nucleic acid volumes is combined with a molecular diagnostic reagent of a set of molecular diagnostic reagents. In the second variation of Step S450, the set of molecular diagnostic reagents preferably comprises different molecular diagnostic reagents, such that different molecular diagnostic protocols analyzing different markers may be performed. Thus, the second variation encompasses running multiple substantially different tests using a stock biological sample, and running substantially different tests using substantially different biological samples (e.g., from different sources)”)</p> <p>U.S. Patent No. 9,050,594 at 31:20-31 (“In a specific example of Step S450, a multichannel liquid handling system aspirates approximately 18 μL of each of a set of nucleic acid volumes from the microfluidic cartridge used in the specific example of Step S440 using a set of pipette tips, punctures at least one foil seal 195 of at least one assay strip, wherein each well of the at least one assay strip contains molecular diagnostic reagents, and dispenses each aspirated nucleic acid volume into a well of the assay strip. In the specific example of S450, the multichannel liquid handling system then aspirates and dispenses the contents of each well approximately 10 times to reconstitute molecular diagnostic reagents and mix the contents of each well.”)</p>

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1(i)	the second module comprising, a plurality of receptacles comprising PCR reagents, wherein a receptacle of the plurality of receptacles is configured to receive nucleic acid extracted from a sample of the plurality of nucleic acid-containing samples; and	<p data-bbox="562 228 2024 342">In the accused system, the second module comprises a plurality of receptacles comprising PCR reagents, wherein a receptacle of the plurality of receptacles is configured to receive nucleic acid extracted from a sample of the plurality of nucleic acid-containing samples.</p> <p data-bbox="562 375 2024 488"><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul data-bbox="615 488 2024 748" style="list-style-type: none"> • “Liquid Handling Processing C: The Test Strip. After piercing the test strip, the liquid handling robot moves to the PCR port or p-port of the microfluidic cartridge, where it aspirates the eluate out of the cartridge into the pipette tip. Once the aspiration step is complete, the eluate is delivered to the appropriate wells in the NeuMoDx test strip, where it is dispensed and aspirated ten times to ensure homogeneous resuspension of the NeuDry PCR reagents. The sample mixes with primers and probes.” <i>Id.</i> at 3:12-3:57. • <i>Id.</i> at 3:36 (showing the liquid handling robot at the test strip)  <p data-bbox="1402 1198 1560 1247">Downloaded on 3/26/2019</p> <p data-bbox="562 1308 2024 1390"><i>NeuMoDx Molecular N288 System</i>, http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ TECHNOLOGY” hyperlink at https://player.vimeo.com/video/281470603. (Exhibit 17)</p> <ul data-bbox="615 1390 1010 1424" style="list-style-type: none"> • At 1:22 (showing reagents)

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		<div data-bbox="564 228 1619 821"><p>Place test strips, reagents and consumables and patient samples onto carriers</p><p>Downloaded on 3/26/2019</p></div> <ul style="list-style-type: none">• At 4:29 (showing the liquid dispenser at the reagent strip)

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		 <p data-bbox="569 902 1226 935">40600129_D-IFU-GBS-Strip_US-only (Exhibit 60)</p> <ul data-bbox="617 943 2007 1414" style="list-style-type: none"> • “The NeuMoDx System uses a combination of heat, lytic enzyme and extraction reagents to perform cell lysis, DNA extraction and removal of inhibitors. The released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are loaded into the NeuMoDx™ Cartridge where the unbound, non-DNA components are further washed away with NeuMoDx™ WASH Solution and the bound DNA is eluted using NeuMoDx™ RELEASE Solution. The NeuMoDx System then uses the released DNA to rehydrate dried assay reagents containing all the elements necessary for amplification of the GBS-specific target. The dried PCR reagents also contain the components required to amplify a section of the Sample Process Control sequence to enable simultaneous amplification and detection of both target and control DNA sequences. After reconstitution of the dried PCR reagents, the NeuMoDx System dispenses the prepared PCR-ready mixture into one PCR chamber (per specimen) of the NeuMoDx Cartridge. Amplification and detection of the control and target (if present) DNA sequences occur in PCR chamber. The chamber and the cartridge are designed to contain the amplicon following real-time-PCR and essentially eliminate contamination risk post-amplification.”

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		<p><i>Id.</i> at 1.</p> <ul style="list-style-type: none"> • “NeuMoDx™ GBS Test Strip: Dried PCR reagents containing GBS-specific TaqMan® probe and primers along with Sample Process Control-specific TaqMan® probe and primers.” <i>Id.</i> at 2. <p>40600147_D-IFU-NeuMoDx-LDT-Test-Strip-US-ONLY (Exhibit 61)</p> <ul style="list-style-type: none"> • “The NeuMoDx™ LDT Test Strip is an empty 16-well strip which is utilized for laboratory developed tests (LDTs) on the NeuMoDx™ 288 NeuMoDx™ and 96 Molecular System (NeuMoDx™ System(s)). NeuMoDx Systems in conjunction with other NeuMoDx™ reagents such as NeuMoDx™ Extraction Plate, NeuMoDx™ lysis buffers, NeuMoDx™ WASH Solution and the NeuMoDx™ RELEASE Solution makes the development of LDTs streamlined and efficient as it combines sample extraction with Real Time PCR in one system. The NeuMoDx LDT Test Strip is universally used for all LDTs processed on either NeuMoDx System.” <i>Id.</i> at 1. • “The NeuMoDx LDT Test Strip is a foil-covered, empty, 16-well disposable plastic strip into which the user pipets assay-specific primers and probe(s) to process LDTs on a NeuMoDx System. It is used in parallel with NeuMoDx™ LDT Master Mix Test Strip, DNA or RNA which contain the required elements for real-time PCR including the Taq DNA polymerase, Reverse Transcriptase (if required), dNTPs, MgCl₂ and other buffer components.” <i>Id.</i> • “The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx WASH Solution and the bound nucleic acid is eluted using the NeuMoDx RELEASE Solution. The NeuMoDx System mixes the released nucleic acid with the user provided LDT primers and probe(s) in the NeuMoDx LDT Test Strip and then uses an aliquot of this solution to rehydrate the dried assay reagents in the appropriate NeuMoDx LDT Master Mix Test Strip (DNA or RNA). Upon mixing with the user-provided primers & probe(s) (LDT-specific reagents) and reconstitution of the dried PCR reagents, the NeuMoDx System will dispense the prepared PCR-ready mixture into the NeuMoDx Cartridge where Real-Time PCR occurs.” <i>Id.</i> <p>40600146_D-IFU-NeuMoDx-LDT-Master-Mix-RNA-US-ONLY (Exhibit 62)</p> <ul style="list-style-type: none"> • “The NeuMoDx™ LDT Master Mix Test Strip, RNA (NeuMoDx™ LDT MM Test Strip, RNA) is a 16-well strip that contains a proprietary, room temperature stable, real-time PCR master mix reagent that when used in conjunction with assay specific primers and probe(s) enables a laboratory to

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		<p>rapidly develop and implement laboratory developed tests (LDTs) on the NeuMoDx™ 288 and NeuMoDx™ 96 Molecular System (NeuMoDx™ System(s)). Other than the LDT specific primers and probe(s), the NeuMoDx LDT MM Test Strip, RNA incorporates all the reagents required for real-time RT-PCR. Once validated by the user's laboratory as part of the LDT, this reagent can be used as a key component for rapid automation of the LDT." <i>Id.</i> at 1.</p> <ul style="list-style-type: none"> • "Laboratory developed tests incorporating the NeuMoDx LDT MM Test Strip, RNA and implemented on the NeuMoDx System offer clinical laboratories a simple, efficient, and straightforward way to rapidly integrate LDTs for sample to result operation. The NeuMoDx System incorporates extraction, purification, quantification and results interpretation. The System provides the opportunity to combine a universal nucleic acid isolation process with the NeuMoDx LDT MM Test Strip, RNA and general real-time, reverse transcription (RT) - PCR reagents, delivering highly accurate results for LDTs from unprocessed clinical samples. The user simply provides assay specific primers and probe(s) on a separate empty NeuMoDx™ LDT Test Strip [REF 100400] and defines the desired real-time, RT-PCR thermal profile. Once the clinical specimens and assay-specific reagents are loaded on the NeuMoDx System, the System automatically starts processing the samples." <i>Id.</i> • "The NeuMoDx Systems use a combination of heat, lytic enzymes, and extraction reagents to perform cell lysis, RNA extraction and removal of inhibitors from unprocessed clinical specimens prior to presenting the extracted RNA for detection by real-time RT-PCR. Upon lysis, the released nucleic acids are captured by magnetic affinity microspheres. The microspheres, with the bound nucleic acids, are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx™ WASH Solution and the bound RNA is eluted using NeuMoDx™ RELEASE Solution. The NeuMoDx System mixes the released RNA with the user provided LDT primers and probe(s) and then uses an aliquot of this solution to rehydrate the dried RT-PCR reagents in the NeuMoDx LDT MM Test Strip, RNA, which contains all the reagents necessary to perform a one-step real-time RT-PCR reaction - specifically Reverse Transcriptase, Taq DNA polymerase, dNTPS, MgCl2 and other optimized excipients and buffering agents as well as the primers and probe specific for the Sample Process Control 2 (SPC2) sequence to enable simultaneous amplification and detection of both target and control RNA sequences. The dried RT-PCR reagents in the NeuMoDx LDT MM Test Strip, RNA do not contain any LDT specific primers or probes (assay specific reagents) other than the SPC2 primers and probe; the assay specific reagents must be added by the user to the NeuMoDx LDT Test Strip. Upon mixing with the user-provided primers & probe(s) and reconstitution of the dried RT-PCR reagents the NeuMoDx System dispenses the prepared

Claim	Claim Language	Infringement Evidence
		<p>RT-PCR-ready mixture into the NeuMoDx Cartridge. Amplification and detection of the control and target (if present) RNA sequences occur in the PCR chamber of the cartridge. The chamber and the cartridge are designed to contain the amplicon following RT-PCR and virtually eliminate contamination risk post-amplification.” <i>Id.</i> at 2.</p> <ul style="list-style-type: none"> • “NeuMoDx™ LDT Master Mix Test Strip, RNA: Dried RT-PCR reagents containing Sample Process Control 2 specific TaqMan® probe and primers.” <i>Id.</i> at 3. <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> • Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10. • U.S. Patent No. 9,382,532 at 11:2-23 (“In one variation, the nucleic acid sample eluted from the microparticles can be aspirated (e.g., by a pipette tip or by a fluid handling system) into another process chamber and combined with process reagents for further processing and characterization. In a specific example of this variation, a system (such as the one described in U.S. patent application Ser. No. 13/766,359, entitled "System and Method for Processing and Detecting Nucleic Acids") can be used to aspirate the nucleic acid sample from a fluidic pathway of a cartridge (such as the one described in U.S. patent application Ser. No. 13/765,996, entitled "Microfluidic Cartridge for Processing and

Claim	Claim Language	Infringement Evidence
		<p>Detecting Nucleic Acids"), while the microparticles are immobilized by a magnet. The system can then combine the nucleic acid sample with process reagents (e.g., PCR reagents) in a separate container (e.g., assay plate), and then transfer the nucleic acid sample combined with process reagents to a detection chamber of the fluidic pathway (upon occlusion and/or opening of the fluidic channel at another subset of occlusion positions). The nucleic acid sample combined with process reagents can then be processed within a diagnostic chamber that is coupled to the fluidic pathway.”)</p> <ul style="list-style-type: none"> Patent No. 9,382,532 at 25:51-26:10 (“Thereafter in the first illustration, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”) Patent No. 9,382,532 at 28:324 (“Thereafter, in the second illustration, the occlusions at the first and eleventh occlusion positions 142', 159' are reversed, defining a sixth truncated pathway, the entire released nucleic acid sample (e.g. -15 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent mixture stored off of the microfluidic cartridge 100. During the reconstitution process, the occlusion at the sixth occlusion position 147' may be reversed, thus defining a seventh truncated pathway. Once reconstitution of the molecular diagnostic reagent mixture with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be aspirated through the reagent port 115 through the seventh truncated pathway to the detection chamber 117, completely filling the detection chamber 117, after which the fluidic pathway 165' is be occluded at third,

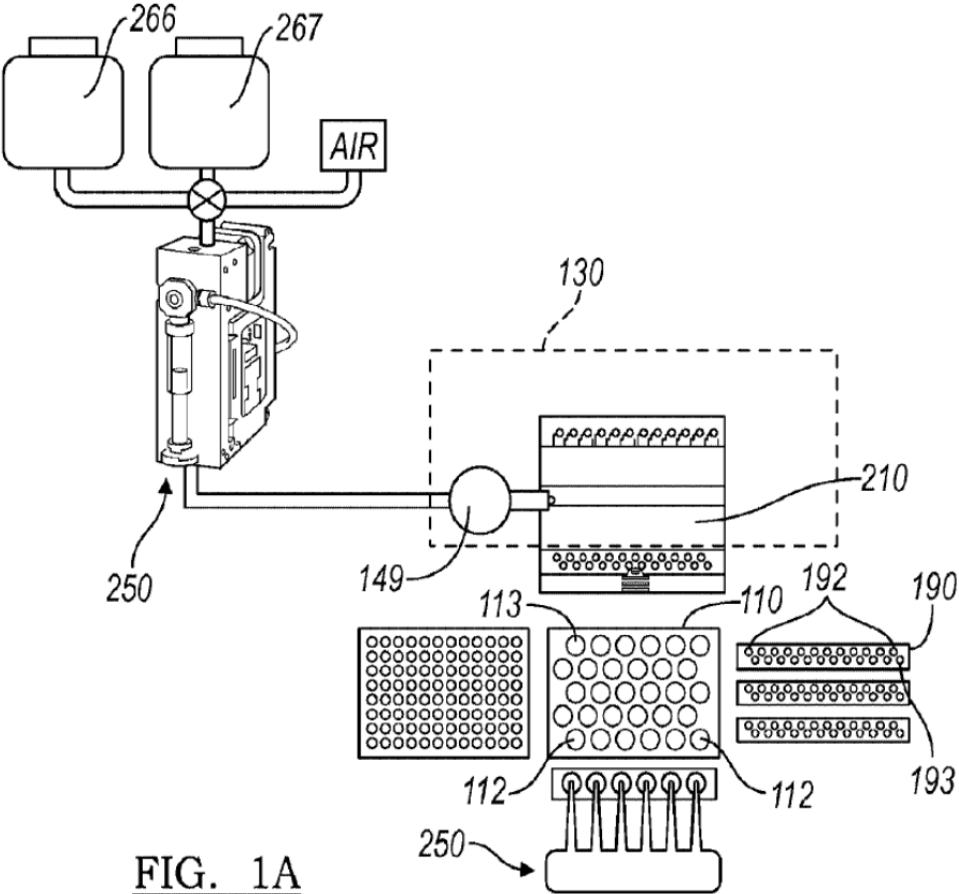
Claim	Claim Language	Infringement Evidence
		<p>seventh, eighth, and ninth occlusion positions 144', 148', 149', 157' defining an eighth truncated pathway. An external molecular diagnostic system and/or module may then perform additional processes on the volume of fluid within the detection chamber 117.”)</p> <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> • Claims 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position of the fluidic pathway, by way of the void of the corrugated surface, the fluidic pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber. • Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate. • U.S. Patent No. 9,403,165 at 3:53-4:9 (“Each sample-port reagent port pair 113 of an embodiment of the top layer 110 also comprises a reagent port 115, as shown in FIG. 1A. The reagent port 115 in a sample port-reagent port pair 113 functions to receive a volume of fluid comprising a reagent used in molecular diagnostics, for delivery of the volume of fluid comprising a reagent to a portion of a fluidic pathway 165 coupled to the sample port-reagent port pair 113. In a specific embodiment, the volume of fluid comprising a reagent used in molecular diagnostics is a sample of reconstituted molecular diagnostic reagents mixed with nucleic acids released and isolated using the microfluidic cartridge

Claim	Claim Language	Infringement Evidence
		<p>100; however, the volume of fluid comprising a reagent used in molecular diagnostics may alternatively be any appropriate fluid comprising reagents used in molecular diagnostics. Preferably, each reagent port 115 is isolated from all other reagent ports, in order to prevent cross-contamination between samples of nucleic acids being analyzed. Additionally, each reagent port 115 is preferably of an appropriate geometric size to accommodate a standard-size pipette tip used to deliver the volume of fluid comprising a reagent used in molecular diagnostics. Alternatively, all or a portion of the reagent ports 115 are configured to be coupled to fluid conduits or tubing that deliver the volume of fluid comprising a reagent used in molecular diagnostics.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,403,165 at 17:6-33 (“Thereafter in the first embodiment, as shown in FIG. H the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 micro liters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”) • U.S. Patent No. 9,403,165 at 19:26-46 (“Thereafter, in the second embodiment, the occlusions at the first and eleventh occlusion positions 142', 159' are reversed, defining a sixth truncated pathway, the entire released nucleic acid sample (e.g. -15 micro liters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent mixture stored off of the microfluidic cartridge 100. During the reconstitution process, the occlusion at the sixth occlusion position 147' may be reversed, thus defining a seventh truncated pathway. Once reconstitution of the molecular diagnostic reagent mixture with the

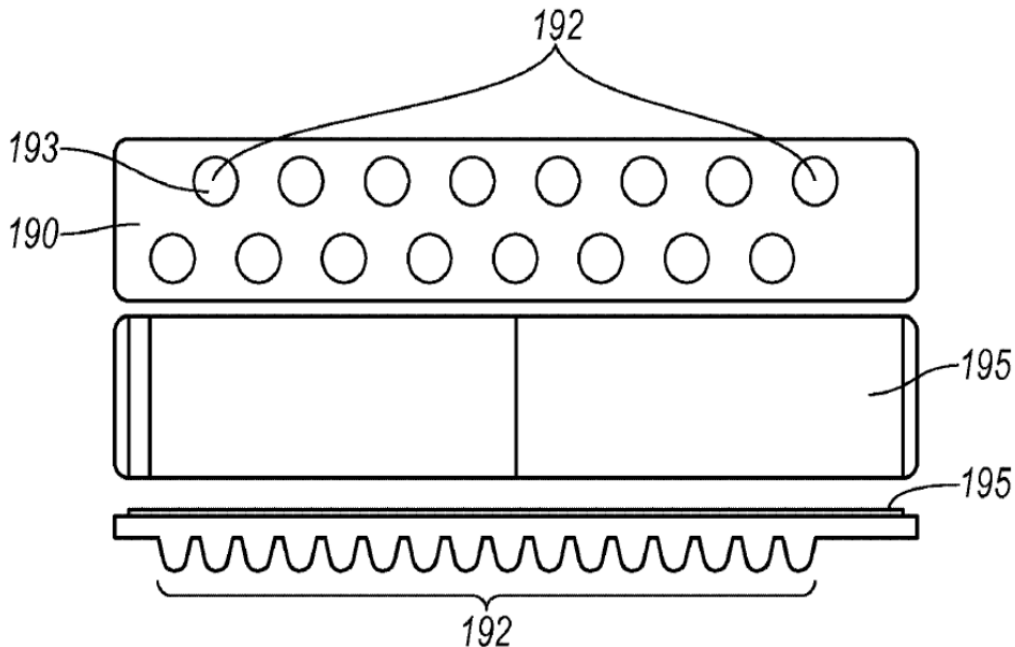
Claim	Claim Language	Infringement Evidence
		<p>released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be aspirated through the reagent port 115 through the seventh truncated pathway to the detection chamber 117, completely filling the detection chamber 117, after which the fluidic pathway 165' is be occluded at third, seventh, eighth, and ninth occlusion positions 144', 148', 149', 157' defining an eighth truncated pathway. An external molecular diagnostic system and/or module may then perform additional processes on the volume of fluid within the detection chamber 117.”)</p> <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • Claim 14. The system of claim 1, wherein the liquid handling system comprises a multichannel pipette head and a syringe pump. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from

Claim	Claim Language	Infringement Evidence
		<p>the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 21. The system of claim 16, wherein the liquid handling system comprises a multichannel pipette head and a syringe pump. • Claim 23. A system for processing and detecting nucleic acids, comprising: a molecular diagnostic module, configured to process a set of biological samples combined with magnetic beads and separate a set of nucleic acid volumes from the set of biological samples combined with magnetic beads, wherein the molecular diagnostic module comprises an actuator configured to displace a cartridge, a set of pins, and at least one cam contacting the set of pins, wherein an extension or retraction of the actuator moves the cartridge, and a displacement of a subset of the set of pins defines a set of pathways in the cartridge, each configured to receive a biological sample combined with magnetic beads of the set of biological samples combined with magnetic beads. • Claim 24. The system of claim 23, further comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample, a lysing reagent, and a sample process control, wherein the capture plate facilitates production of at least one biological sample combined with magnetic beads; an assay strip comprising at least one reagent well containing a molecular diagnostic reagent volume configured to be combined with a nucleic acid volume of the set of nucleic acid volumes to produce at least one nucleic acid-reagent mixture; and a liquid handling system configured to transfer at least one biological sample combined with magnetic beads from the capture plate to the molecular diagnostic module, transfer at least one nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer at least one nucleic acid-reagent mixture from the assay strip back to the molecular diagnostic module. • Claim 32. The system of claim 24, wherein the liquid handling system comprises a multichannel pipette head and a syringe pump. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids

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		<p>from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.")</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 2:49-3:1 ("As shown in FIGS. 1A-1B and 7A, an embodiment of a system 100 for processing and detecting nucleic acids comprises: a capture plate 110 configured to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119; a molecular diagnostic module 130 comprising a microfluidic cartridge receiving module 140, heating and cooling subsystem 150, a magnet 160, a valve actuation subsystem 170, an optical subsystem 180; and an assay strip 190 configured to facilitate mixing of molecular diagnostic reagents with a nucleic acid volume. Other embodiments of the system 100 may further comprise at least one of a capture plate module 120 configured to support the capture plate 110; a filter 200 and filter holder 205 to facilitate sample preparation; a microfluidic cartridge 210 configured to facilitate sample processing; an assay strip holder 230; an assay strip carrier 240; a liquid handling system 250 configured to facilitate gas and fluid delivery to different elements of the system 100; a processor configured to analyze data resulting from a run of the system 100; and a user interface configured to allow a user to interact with the system 100.") • U.S. Patent No. 9,050,594 at FIG. 1A.

Claim	Claim Language	Infringement Evidence
		 <p style="text-align: center;">FIG. 1A</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 3:14-46 (“In one example workflow of the system 100, a liquid handling system 250 aspirates a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), and dispenses the set of biological samples into a capture plate 110 to be lysed and combined with magnetic beads (containing a proprietary affinity coating to bind the nucleic acids to the magnetic beads) by a capture plate module 120. The liquid handling system 250 then aspirates substantially all of each sample of the set of lysed biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate no [sic], and dispenses the set of magnetic bead-samples into a

Claim	Claim Language	Infringement Evidence
		<p>microfluidic cartridge 210, aligned within a cartridge receiving module 140 of a molecular diagnostic module 130, and configured to be manipulated by the molecular diagnostic module 130. A heating and cooling subsystem 150, a magnet 160, and a valve actuation subsystem 170 of the molecular diagnostic module 130 then facilitate separation of a set of nucleic acids from the magnetic bead-samples, as the liquid handling system 250 dispenses wash solutions, release solutions, and/or air at appropriate stages. The liquid handling system 250 then aspirates the set of nucleic acids from the microfluidic cartridge 210 contained within the molecular diagnostic module 130, combines the set of nucleic acids with a set of molecular diagnostic reagents using an assay strip 190, and dispenses the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the microfluidic cartridge 210 within the molecular diagnostic module 130. The detection chamber heaters 157, optical subsystem 180 and valve actuation subsystem 170 of the molecular diagnostic module 130 then facilitate analysis of the set of nucleic acid-reagent mixtures by a processor configured to display information on a user interface.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 19:45-65 (“As shown in FIGS. 18A and 18B, the assay strip 190 comprises an assay strip substrate 191 comprising a set of wells 192, and typically a puncturable foil seal 195, and functions to facilitate combination of a set of nucleic acid samples with a set of molecular diagnostic reagents for amplification and/or detection of a nucleic acid sequence or sequences. Preferably, the entire assay strip 190 is configured to be a consumable (i.e., disposable), such that the assay strip 190 can be used during multiple runs of the system 100, then the assay strip 190 is disposed of once all of the wells 192, containing unitized reagents for a single test or group of tests, is exhausted. Alternatively, at least a portion of the assay strip 190 is configured to be reusable, such that wells may be reloaded with reagents and reused with the system 100. In one variation of the assay strip 190, the assay strip substrate 191 is reusable, while the puncturable foil seal 195 is disposable and replaced after each run of the system 100. In another variation, the reusable assay strip substrate 191 does not require a puncturable foil seal 195, such that reagents specific to a certain nucleic acid sequences may be deposited into open wells of the assay strip substrate 191 by a user.”) • U.S. Patent No. 9,050,594 at FIG. 18A.


Claim	Claim Language	Infringement Evidence
		 <p style="text-align: center;">FIG. 18A</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 20:12-15 (“The set of wells 192 of the assay strip substrate 191 function to receive at least one nucleic acid sample, and to facilitate combination of the nucleic acid sample with at least one of a set of molecular diagnostic reagents.”) U.S. Patent No. 9,050,594 at 21:46-22:3 (“As described earlier, the assay strip 190 may be configured to be received by an assay strip holder 230. The assay strip holder 230 functions to receive and align multiple assay strips 190, such that a multichannel pipettor or other fluid delivery system may combine multiple nucleic acid samples with molecular diagnostic reagents using wells 193 of multiple assay strips 190. In one variation, the assay strip holder 230 may be configured to contain Assay strips 190 including reagents for substantially different molecular diagnostic assays, as shown in FIG. 17B, such that a single run of the system 100 involves analyzing a set of nucleic acid samples under different molecular diagnostic assays. In another variation, the assay strip holder 230 may be configured to contain assay strips 190 including reagents for identical molecular diagnostic assays, such that a single


Claim	Claim Language	Infringement Evidence
		<p>run of the system 100 involves analyzing a set of nucleic acid samples under the same molecular diagnostic assay. Preferably, the assay strip holder 230 is composed of a material that is dishwasher safe and autoclavable, configured to hold the assay strips 190 in place during handling by a fluid delivery system (e.g., pipettor), and configured such that the assay strips 190 avoid protruding over an edge of the assay strip holder 230, but the assay strip holder 230 is constructed to facilitate insertion and removal of the assay strips 190 from the assay strip holder 230.”)</p> <ul style="list-style-type: none"> <p>U.S. Patent No. 9,050,594 at 23:28-58 (“The liquid handling system 250 of the system 100 includes a liquid handling arm 255 and a syringe pump 265, as shown in FIGS. 14A-14C and functions to deliver biological samples, reagents, and gases to elements of the system 100. As described in Section 1, an embodiment of the liquid handling system 250 is configured to aspirate a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), dispense the set of biological samples into a capture plate no [sic] to be lysed and combined with magnetic beads by a capture plate module 120, aspirate the set of biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate 110, and dispense the set of magnetic bead-samples into microfluidic cartridge 210 located in a molecular diagnostic module 130. The embodiment of the liquid handling system 100 is further configured to facilitate separation of a set of nucleic acids from the magnetic bead-samples, by dispensing a wash solution, a release solution, and/or air into the molecular diagnostic module 130, by the nozzle 149 coupled to the linear actuator 146, at appropriate stages, aspirate the set of nucleic acids from the molecular diagnostic module 130, combine the set of nucleic acids with a set of molecular diagnostic reagents using an assay strip 190, and dispense the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the molecular diagnostic module 130 for further processing and analysis. [Other embodiments of the liquid handling system 250 may be configured to perform alternative molecular diagnostic assay protocols and/or dispense and aspirate alternative fluids into and from other elements supporting a molecular diagnostic protocol.”)</p> <p>U.S. Patent No. 9,050,594 at 30:27-53 (“Step S450 recites combining each nucleic acid volume of the set of nucleic acid volumes with a molecular diagnostic reagent of a set of molecular diagnostic reagents to produce a set of nucleic acid-reagent mixtures, which functions to prepare the set of nucleic acid volumes to be detected. For each nucleic acid volume in the set of nucleic acid volumes, Step S450 preferably comprises aspirating an entire volume of the nucleic acid volume from its corresponding fluidic pathway, and transferring the nucleic acid volume to a well containing a molecular diagnostic reagent. Preferably, all nucleic acid volumes in the set of nucleic acid volumes</p>

Claim	Claim Language	Infringement Evidence
		<p>are aspirated and combined with molecular diagnostic reagents simultaneously using a multichannel fluid delivery system; however, each nucleic acid volume in the set of nucleic acid volumes may alternatively be aspirated and combined with molecular diagnostic reagents independently of the other nucleic acid volumes. The molecular diagnostic reagents preferably comprise reagents configured to analyze the set of nucleic acid volumes for markers of at least one of gonorrhea (GC), Chlamydia (CT), herpes simplex virus (HSV), human immunodeficiency virus (HIV), human respiratory diseases, vaginal diseases, hepatitis C virus (HCV), hepatitis B virus (HBV), trichomonas, group B streptococcus (GBS), factor 2 (FII) gene, and factor five (FV) gene, but may alternatively comprise reagents used to detect any specific nucleic acid sequence.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 30:54-31:6 (“In a first variation of Step S450 as shown in FIG. 16A, a nucleic acid volume is aspirated and combined with a molecular diagnostic reagent for a single assay. In the first variation of Step S450, a set of nucleic acid volumes may thus be aspirated simultaneously, and each nucleic acid volume may be transferred to an individual well to be combined with a molecular diagnostic reagent of a set of molecular diagnostic reagents to produce a set of nucleic acid-reagent mixtures. In the first variation of Step S450, all nucleic acid-reagent mixtures in the set of nucleic acid-reagent mixtures may or may not be substantially identical in composition, depending on the homogeneity of the biological samples used in Step S410; however, the first variation of S450 preferably comprises using identical molecular diagnostic reagents, such that identical molecular diagnostic protocols analyzing identical markers may be performed. Thus, the first variation of Step S450 encompasses running multiple identical tests from a stock biological sample (e.g., a multiplex assay), and running identical tests using a set of substantially different biological samples (e.g., from different sources).”) • U.S. Patent No. 9,050,594 at 31:7-19 (“In a second variation of Step S450, as shown in FIG. 16B, the set of nucleic acid volumes is aspirated, and each nucleic acid volume in the set of nucleic acid volumes is combined with a molecular diagnostic reagent of a set of molecular diagnostic reagents. In the second variation of Step S450, the set of molecular diagnostic reagents preferably comprises different molecular diagnostic reagents, such that different molecular diagnostic protocols analyzing different markers may be performed. Thus, the second variation encompasses running multiple substantially different tests using a stock biological sample, and running substantially different tests using substantially different biological samples (e.g., from different sources).”) • U.S. Patent No. 9,050,594 at 31:20-31 (“In a specific example of Step S450, a multichannel liquid handling system aspirates approximately 18 μL of each of a set of nucleic acid volumes from the

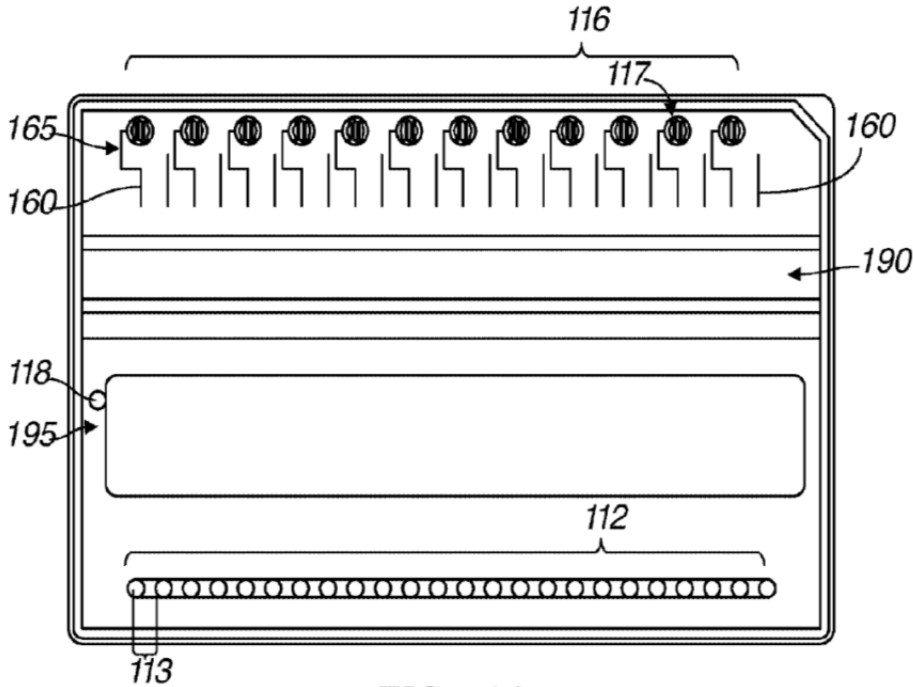
Claim	Claim Language	Infringement Evidence
		<p>microfluidic cartridge used in the specific example of Step S440 using a set of pipette tips, punctures at least one foil seal 195 of at least one assay strip, wherein each well of the at least one assay strip contains molecular diagnostic reagents, and dispenses each aspirated nucleic acid volume into a well of the assay strip. In the specific example of S450, the multichannel liquid handling system then aspirates and dispenses the contents of each well approximately 10 times to reconstitute molecular diagnostic reagents and mix the contents of each well.”)</p>
1(j)	<p>a liquid dispenser configured to dispense or withdraw liquid from the plurality of sample tubes and dispense or withdraw liquid from the plurality of receptacles comprising PCR reagents.</p>	<p>The accused system comprises a liquid dispenser configured to dispense or withdraw liquid from the plurality of sample tubes and dispense or withdraw liquid from the plurality of receptacles comprising PCR reagents.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “Liquid Handling Processing C: The Test Strip. After piercing the test strip, the liquid handling robot moves to the PCR port or p-port of the microfluidic cartridge, where it aspirates the eluate out of the cartridge into the pipette tip. Once the aspiration step is complete, the eluate is delivered to the appropriate wells in the NeuMoDx test strip, where it is dispensed and aspirated ten times to ensure homogeneous resuspension of the NeuDry PCR reagents. The sample mixes with primers and probes.” <i>Id.</i> at 3:12-3:57. • <i>Id.</i> at 3:36 (showing the liquid handling robot at the test strip)

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		<div data-bbox="661 228 1602 760"></div> <p><i>NeuMoDx Molecular N288 System</i>, http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ TECHNOLOGY” hyperlink at https://player.vimeo.com/video/281470603. (Exhibit 17)</p> <ul style="list-style-type: none">• At 3:10 (showing al liquid dispenser at a sample tube)

Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none">• At 4:29 (showing the liquid dispenser at the reagent strip)

Claim	Claim Language	Infringement Evidence
		 <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> • Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position of the fluidic pathway, by way of the void of the corrugated surface, the fluidic pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber. • Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly

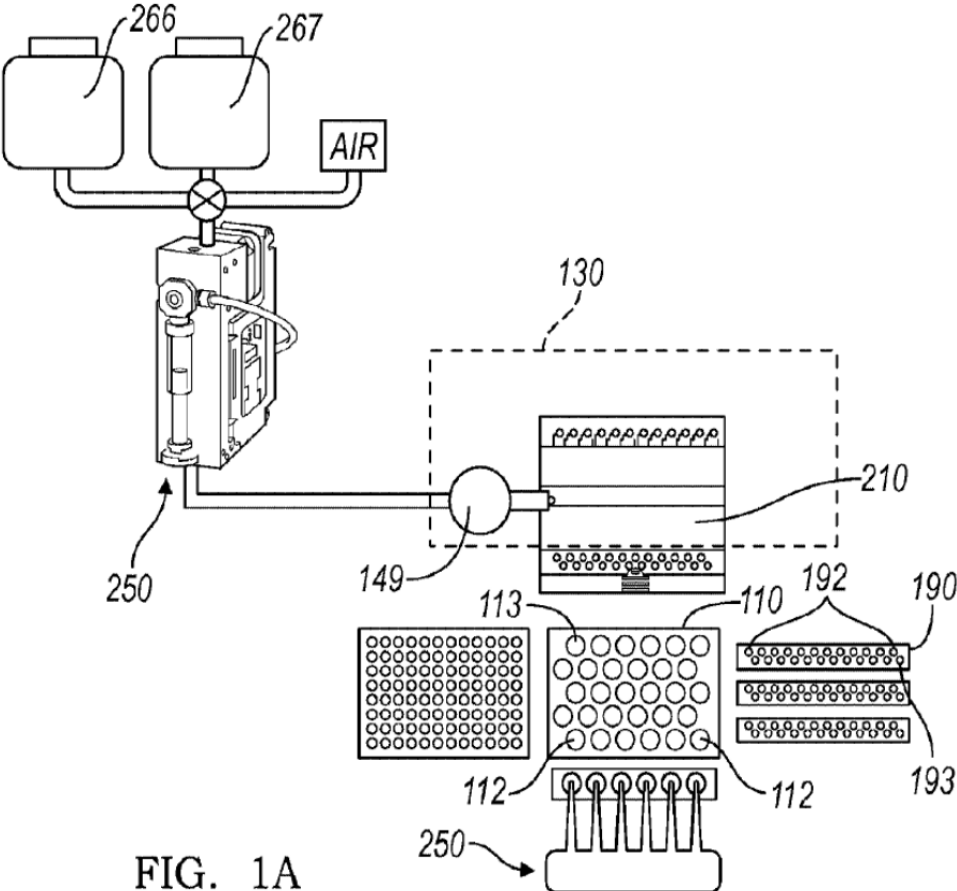
Claim	Claim Language	Infringement Evidence
		<p>opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate.</p> <ul style="list-style-type: none"> • Claim 10. The cartridge of claim 8, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the second detection chamber, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port. • U.S. Patent No. 9,403,165 at 3:33-3:52 (“Each sample-port-reagent port pair 113 of an embodiment of the top layer 110 comprises a sample port 114 and a reagent port 115. The sample port 114 functions to receive a volume of a sample fluid potentially containing the nucleic acids of interest for delivery of the volume of fluid to a portion of a fluidic pathway 165 coupled to the sample port-reagent port pair 113. In a specific embodiment, the volume of a sample fluid is a biological sample with magnetic beads for nucleic acid isolation; however, the volume of fluid comprising a sample fluid may alternatively be any appropriate fluid containing a sample with nucleic acids. Preferably, each sample port 114 is isolated from all other sample ports, in order to prevent cross-contamination between samples of nucleic acids being analyzed. Additionally, each sample port 114 is preferably of an appropriate geometric size and shape to accommodate a standard-size pipette tip used to deliver the volume of a sample fluid without leaking. Alternatively, all or a portion of the sample ports 114 are configured to be coupled to fluid conduits or tubing that deliver the volume of a sample fluid.”) • U.S. Patent No. 9,403,165 at 3:53-4:9 (“Each sample-port reagent port pair 113 of an embodiment of the top layer 110 also comprises a reagent port 115, as shown in FIG. 1A. The reagent port 115 in a sample port-reagent port pair 113 functions to receive a volume of fluid comprising a reagent used in molecular diagnostics, for delivery of the volume of fluid comprising a reagent to a portion of a fluidic pathway 165 coupled to the sample port-reagent port pair 113. In a specific embodiment, the volume of fluid comprising a reagent used in molecular diagnostics is a sample of reconstituted molecular

Claim	Claim Language	Infringement Evidence
		<p>diagnostic reagents mixed with nucleic acids released and isolated using the microfluidic cartridge 100; however, the volume of fluid comprising a reagent used in molecular diagnostics may alternatively be any appropriate fluid comprising reagents used in molecular diagnostics. Preferably, each reagent port 115 is isolated from all other reagent ports, in order to prevent cross-contamination between samples of nucleic acids being analyzed. Additionally, each reagent port 115 is preferably of an appropriate geometric size to accommodate a standard-size pipette tip used to deliver the volume of fluid comprising a reagent used in molecular diagnostics. Alternatively, all or a portion of the reagent ports 115 are configured to be coupled to fluid conduits or tubing that deliver the volume of fluid comprising a reagent used in molecular diagnostics.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at 1A.  <p style="text-align: center;">FIG. 1A</p> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at 17:6-33 (“Thereafter in the first embodiment, as shown in FIG. H the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 micro liters) may be aspirated

Claim	Claim Language	Infringement Evidence
		<p>out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at 19:26-46 (“Thereafter, in the second embodiment, the occlusions at the first and eleventh occlusion positions 142', 159' are reversed, defining a sixth truncated pathway, the entire released nucleic acid sample (e.g. -15 micro liters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent mixture stored off of the microfluidic cartridge 100. During the reconstitution process, the occlusion at the sixth occlusion position 147' may be reversed, thus defining a seventh truncated pathway. Once reconstitution of the molecular diagnostic reagent mixture with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be aspirated through the reagent port 115 through the seventh truncated pathway to the detection chamber 117, completely filling the detection chamber 117, after which the fluidic pathway 165' is be occluded at third, seventh, eighth, and ninth occlusion positions 144', 148', 149', 157' defining an eighth truncated pathway. An external molecular diagnostic system and/or module may then perform additional processes on the volume of fluid within the detection chamber 117.”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample,

Claim	Claim Language	Infringement Evidence
		<p>thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • Claim 14. The system of claim 1, wherein the liquid handling system comprises a multichannel pipette head and a syringe pump. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module. • Claim 23. A system for processing and detecting nucleic acids, comprising: a molecular diagnostic module, configured to process a set of biological samples combined with magnetic beads and separate a set of nucleic acid volumes from the set of biological samples combined with magnetic beads, wherein the molecular diagnostic module comprises an actuator configured to displace a cartridge, a set of pins, and at least one cam contacting the set of pins, wherein an extension or retraction of the actuator moves the cartridge, and a displacement of a subset of the set of pins defines a set of pathways in the cartridge, each configured to receive a biological sample combined with magnetic beads of the set of biological

Claim	Claim Language	Infringement Evidence
		<p>samples combined with magnetic beads.</p> <ul style="list-style-type: none"> • Claim 24. The system of claim 23, further comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample, a lysing reagent, and a sample process control, wherein the capture plate facilitates production of at least one biological sample combined with magnetic beads; an assay strip comprising at least one reagent well containing a molecular diagnostic reagent volume configured to be combined with a nucleic acid volume of the set of nucleic acid volumes to produce at least one nucleic acid-reagent mixture; and a liquid handling system configured to transfer at least one biological sample combined with magnetic beads from the capture plate to the molecular diagnostic module, transfer at least one nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer at least one nucleic acid-reagent mixture from the assay strip back to the molecular diagnostic module. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) • U.S. Patent No. 9,050,594 at 2:49-3:1 (“As shown in FIGS. 1A-1B and 7A, an embodiment of a system 100 for processing and detecting nucleic acids comprises: a capture plate 110 configured to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119; a molecular diagnostic module 130 comprising a microfluidic cartridge receiving module 140, heating and cooling subsystem 150, a magnet 160, a valve actuation subsystem 170, an optical subsystem 180; and an assay strip 190 configured to facilitate mixing of molecular diagnostic reagents with a nucleic acid volume. Other embodiments of the system 100 may further comprise at least one of a capture plate module 120 configured to support the capture plate 110; a filter 200 and filter holder 205 to facilitate sample preparation; a microfluidic cartridge 210 configured to facilitate sample processing; an assay strip holder 230; an assay strip carrier 240; a liquid handling system 250 configured to facilitate gas and fluid delivery to different elements of the system 100; a processor configured to analyze data resulting from

Claim	Claim Language	Infringement Evidence
		<p>a run of the system 100; and a user interface configured to allow a user to interact with the system 100.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at FIG. 1A.  <p style="text-align: center;">FIG. 1A</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 3:14-46 (“In one example workflow of the system 100, a liquid handling system 250 aspirates a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), and dispenses the set of biological samples into a capture plate 110 to be lysed and combined with magnetic beads (containing a proprietary affinity coating to bind the nucleic acids to the magnetic beads) by a capture plate module 120. The liquid handling system 250 then aspirates substantially all of

Claim	Claim Language	Infringement Evidence
		<p>each sample of the set of lysed biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate no [sic], and dispenses the set of magnetic bead-samples into a microfluidic cartridge 210, aligned within a cartridge receiving module 140 of a molecular diagnostic module 130, and configured to be manipulated by the molecular diagnostic module 130. A heating and cooling subsystem 150, a magnet 160, and a valve actuation subsystem 170 of the molecular diagnostic module 130 then facilitate separation of a set of nucleic acids from the magnetic bead-samples, as the liquid handling system 250 dispenses wash solutions, release solutions, and/or air at appropriate stages. The liquid handling system 250 then aspirates the set of nucleic acids from the microfluidic cartridge 210 contained within the molecular diagnostic module 130, combines the set of nucleic acids with a set of molecular diagnostic reagents using an assay strip 190, and dispenses the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the microfluidic cartridge 210 within the molecular diagnostic module 130. The detection chamber heaters 157, optical subsystem 180 and valve actuation subsystem 170 of the molecular diagnostic module 130 then facilitate analysis of the set of nucleic acid-reagent mixtures by a processor configured to display information on a user interface.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 9:32-41 (“Additionally, the extended configuration 146b of the scissor jack actuator is configured to couple the nozzle 149 to a fluid port 222 of the microfluidic cartridge 210, such that the liquid handling system 250 can deliver solutions and gases for processing of biological samples. The linear actuator 146 may alternatively be any appropriate linear actuator, such as a hydraulic, pneumatic, or motor-driven linear actuator, configured to linearly displace a microfluidic cartridge within the molecular diagnostic module 130.”) • U.S. Patent No. 9,050,594 at 21:46-22:3 (“As described earlier, the assay strip 190 may be configured to be received by an assay strip holder 230. The assay strip holder 230 functions to receive and align multiple assay strips 190, such that a multichannel pipettor or other fluid delivery system may combine multiple nucleic acid samples with molecular diagnostic reagents using wells 193 of multiple assay strips 190. In one variation, the assay strip holder 230 may be configured to contain Assay strips 190 including reagents for substantially different molecular diagnostic assays, as shown in FIG. 17B, such that a single run of the system 100 involves analyzing a set of nucleic acid samples under different molecular diagnostic assays. In another variation, the assay strip holder 230 may be configured to contain assay strips 190 including reagents for identical molecular diagnostic assays, such that a single run of the system 100 involves analyzing a set of nucleic acid samples under the same molecular diagnostic assay. Preferably, the assay strip holder 230 is composed of a material that is dishwasher

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		<p>safe and autoclavable, configured to hold the assay strips 190 in place during handling by a fluid delivery system (e.g., pipettor), and configured such that the assay strips 190 avoid protruding over an edge of the assay strip holder 230, but the assay strip holder 230 is constructed to facilitate insertion and removal of the assay strips 190 from the assay strip holder 230.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 23:28-58 (“The liquid handling system 250 of the system 100 includes a liquid handling arm 255 and a syringe pump 265, as shown in FIGS. 14A-14C and functions to deliver biological samples, reagents, and gases to elements of the system 100. As described in Section 1, an embodiment of the liquid handling system 250 is configured to aspirate a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), dispense the set of biological samples into a capture plate no [sic] to be lysed and combined with magnetic beads by a capture plate module 120, aspirate the set of biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate 110, and dispense the set of magnetic bead-samples into microfluidic cartridge 210 located in a molecular diagnostic module 130. The embodiment of the liquid handling system 100 is further configured to facilitate separation of a set of nucleic acids from the magnetic bead-samples, by dispensing a wash solution, a release solution, and/or air into the molecular diagnostic module 130, by the nozzle 149 coupled to the linear actuator 146, at appropriate stages, aspirate the set of nucleic acids from the molecular diagnostic module 130, combine the set of nucleic acids with a set of molecular diagnostic reagents using an assay strip 190, and dispense the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the molecular diagnostic module 130 for further processing and analysis. [Other embodiments of the liquid handling system 250 may be configured to perform alternative molecular diagnostic assay protocols and/or dispense and aspirate alternative fluids into and from other elements supporting a molecular diagnostic protocol.”)

Claim	Claim Language	Infringement Evidence
		<div data-bbox="1171 284 2005 844" data-label="Image"> <p>FIG. 14B</p> </div> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at FIG. 14B. • U.S. Patent No. 9,050,594 at 23:59-67 (“The liquid handling arm 255 comprises a gantry 256 and a multichannel liquid handling head 257, and functions to travel to different elements of the system 100 for fluid delivery and aspiration. The liquid handling arm 255 is preferably automated and configured to move, aspirate, and deliver fluids automatically, but may alternatively be a semi-automated liquid handling arm 255 configured to perform at least one of moving, aspirating, and delivering automatically, while another entity, such as a user, performs the other functions.”) • U.S. Patent No. 9,050,594 at 24:16-25 (“The multichannel liquid handling head 257 functions to aspirate fluids from and deliver fluids to different elements of the system 100. Preferably, the multichannel liquid handling head 257 is a multichannel pipette head; however, the multichannel liquid handling head 257 may alternatively be any appropriate multichannel liquid handling head configured to deliver fluids and/or gases. Preferably, the multichannel liquid handling head 257 comprises at least eight independent channels 258, but may alternatively comprise any number of channels 258 configured to aspirate and deliver fluids.”) • U.S. Patent No. 9,050,594 at 30:28-53 (“Step S450 recites combining each nucleic acid volume of the set of nucleic acid volumes with a molecular diagnostic reagent of a set of molecular diagnostic”)


Claim	Claim Language	Infringement Evidence
		<p>reagents to produce a set of nucleic acid-reagent mixtures, which functions to prepare the set of nucleic acid volumes to be detected. For each nucleic acid volume in the set of nucleic acid volumes, Step S450 preferably comprises aspirating an entire volume of the nucleic acid volume from its corresponding fluidic pathway, and transferring the nucleic acid volume to a well containing a molecular diagnostic reagent. Preferably, all nucleic acid volumes in the set of nucleic acid volumes are aspirated and combined with molecular diagnostic reagents simultaneously using a multichannel fluid delivery system; however, each nucleic acid volume in the set of nucleic acid volumes may alternatively be aspirated and combined with molecular diagnostic reagents independently of the other nucleic acid volumes. The molecular diagnostic reagents preferably comprise reagents configured to analyze the set of nucleic acid volumes for markers of at least one of gonorrhea (GC), Chlamydia (CT), herpes simplex virus (HSV), human immunodeficiency virus (HIV), human respiratory diseases, vaginal diseases, hepatitis C virus (HCV), hepatitis B virus (HBV), trichomonas, group B streptococcus (GBS), factor 2 (FII) gene, and factor five (FV) gene, but may alternatively comprise reagents used to detect any specific nucleic acid sequence.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 30:54-31:6 (“In a first variation of Step S450 as shown in FIG. 16A, a nucleic acid volume is aspirated and combined with a molecular diagnostic reagent for a single assay. In the first variation of Step S450, a set of nucleic acid volumes may thus be aspirated simultaneously, and each nucleic acid volume may be transferred to an individual well to be combined with a molecular diagnostic reagent of a set of molecular diagnostic reagents to produce a set of nucleic acid-reagent mixtures. In the first variation of Step S450, all nucleic acid-reagent mixtures in the set of nucleic acid-reagent mixtures may or may not be substantially identical in composition, depending on the homogeneity of the biological samples used in Step S410; however, the first variation of S450 preferably comprises using identical molecular diagnostic reagents, such that identical molecular diagnostic protocols analyzing identical markers may be performed. Thus, the first variation of Step S450 encompasses running multiple identical tests from a stock biological sample (e.g., a multiplex assay), and running identical tests using a set of substantially different biological samples (e.g., from different sources).”) • U.S. Patent No. 9,050,594 at 31:7-19 (“In a second variation of Step S450, as shown in FIG. 16B, the set of nucleic acid volumes is aspirated, and each nucleic acid volume in the set of nucleic acid volumes is combined with a molecular diagnostic reagent of a set of molecular diagnostic reagents. In the second variation of Step S450, the set of molecular diagnostic reagents preferably comprises different molecular diagnostic reagents, such that different molecular diagnostic protocols analyzing different

Claim	Claim Language	Infringement Evidence
		<p>markers may be performed. Thus, the second variation encompasses running multiple substantially different tests using a stock biological sample, and running substantially different tests using substantially different biological samples (e.g., from different sources)”</p> <ul style="list-style-type: none"> <p>U.S. Patent No. 9,050,594 at 31:20-31 (“In a specific example of Step S450, a multichannel liquid handling system aspirates approximately 18 μL of each of a set of nucleic acid volumes from the microfluidic cartridge used in the specific example of Step S440 using a set of pipette tips, punctures at least one foil seal 195 of at least one assay strip, wherein each well of the at least one assay strip contains molecular diagnostic reagents, and dispenses each aspirated nucleic acid volume into a well of the assay strip. In the specific example of S450, the multichannel liquid handling system then aspirates and dispenses the contents of each well approximately 10 times to reconstitute molecular diagnostic reagents and mix the contents of each well.”)</p>

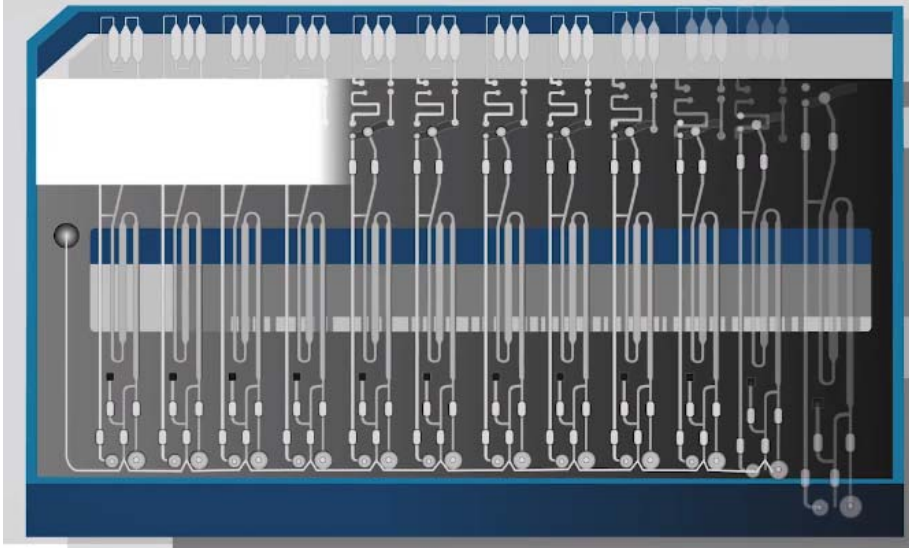
EXHIBIT 92

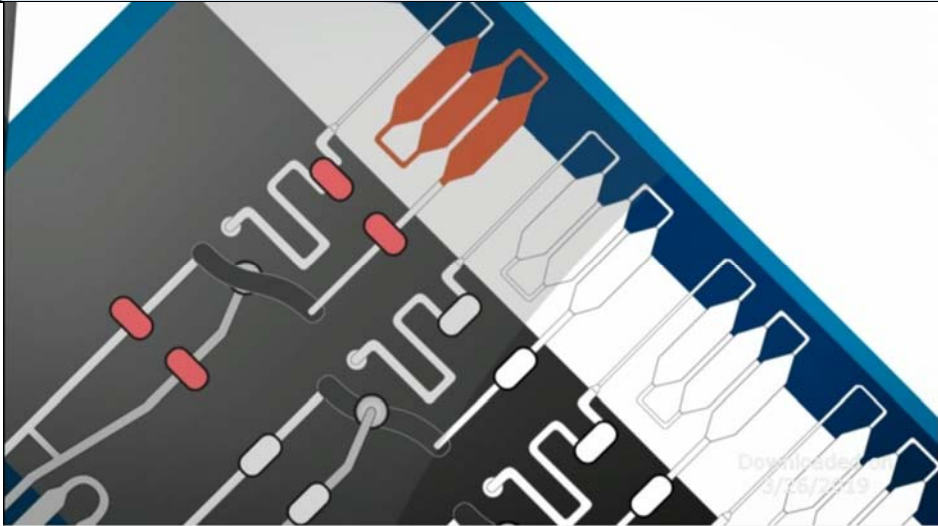
Exhibit 92

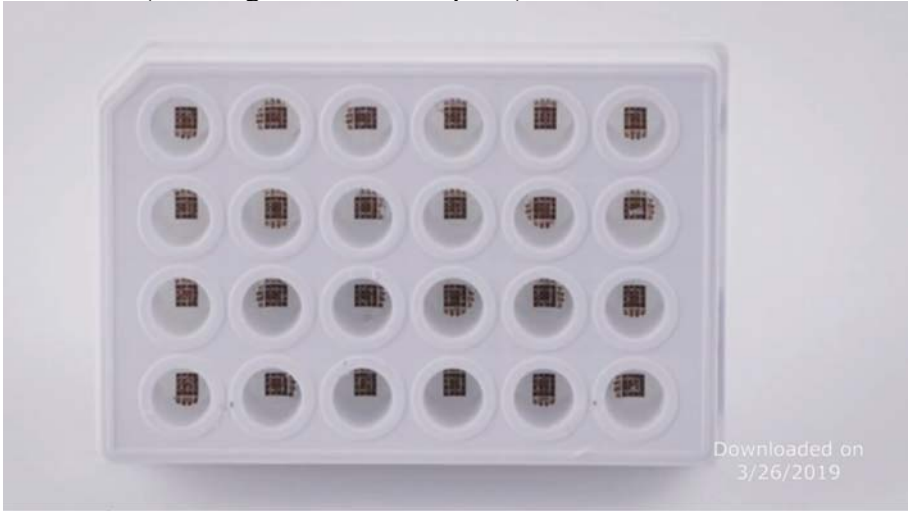
U.S. Patent No. 10,632,466 Infringement Chart

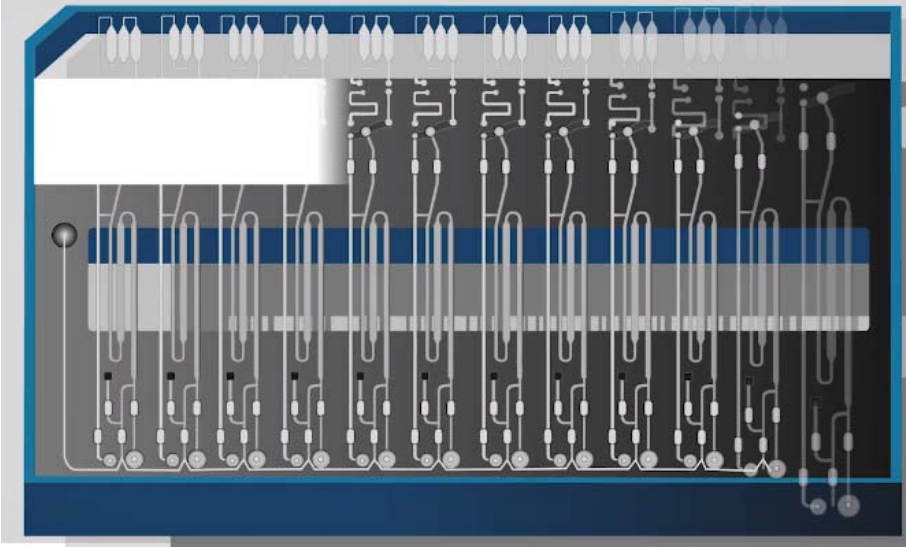
Claim	Claim Language	Infringement Evidence
1(a)	A method of analyzing a plurality of nucleic acid-containing samples, the method comprising	<p>To the extent that the preamble, the accused workflow comprises a method of analyzing a plurality of nucleic acid-containing samples.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-products/, last visited June 5, 2019 (Exhibit 12)</p> 

Claim	Claim Language	Infringement Evidence
		<p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul style="list-style-type: none"> • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result.” <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> • “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieving [sic] optimal operational and clinical performance for our customers and their patients.” • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents. • “The NeuMoDx™ 96 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 288 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 288 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at</p>


Claim	Claim Language	Infringement Evidence
		<p data-bbox="567 235 1291 267">https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> <li data-bbox="615 272 1869 381">• “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59  <ul style="list-style-type: none"> <li data-bbox="615 933 1911 1112">• “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins. During a series of independent heat on-heat off sequences, an optical scanner measures the level of fluorescence emitted, and converts it into the qualitative or quantitative results which are displayed as amplification curves for analysis by the laboratorian.” <i>Id.</i> at 3:58-4:20. <li data-bbox="615 1117 1312 1149">• <i>Id.</i> at 4:08 (showing the three thin PCR chambers).

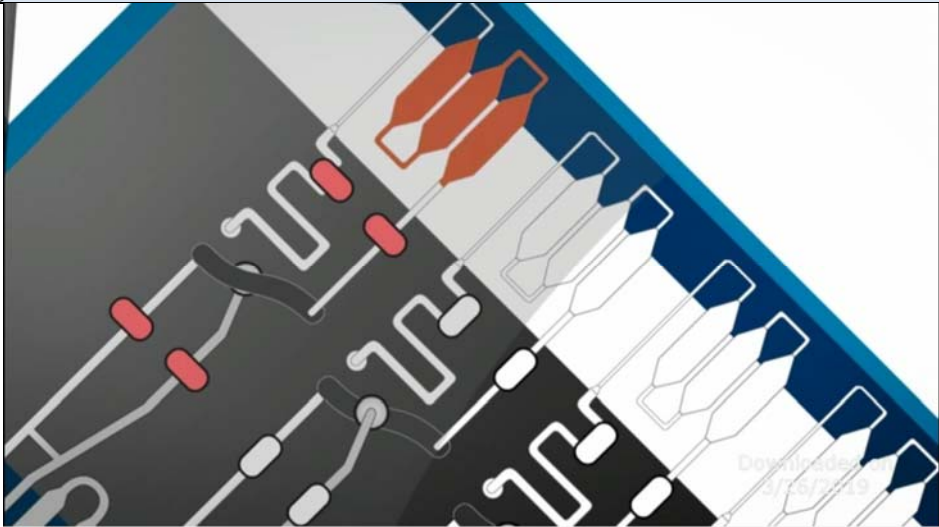
Claim	Claim Language	Infringement Evidence
		 <p><i>NeuMoDxTM Molecular Systems</i>, NEUMODx, http://www.neumodx.com/dr-steven-young-video-testimonial/, hyperlink at https://youtu.be/vukP6gbLBYE. (Exhibit 32)</p> <ul style="list-style-type: none"> At 2:58-3:18 (“There’s two systems that have been put into operation by NeuMoDx. One is the 288. It’s a high-throughput instrument, versus the 96, which is a lower throughput instrument. The advantage is that both systems use all of the same chemistry and all of the same hardware. Its just a smaller footprint.”)
1(b)	extracting nucleic acids from the plurality of nucleic acid-containing samples in a first module and amplifying the nucleic acid extracted from the plurality of nucleic acid-containing samples simultaneously in a second module using a	<p>The accused workflow comprises extracting nucleic acids from the plurality of nucleic acid-containing samples in a first module and amplifying the nucleic acid extracted from the plurality of nucleic acid-containing samples simultaneously in a second module using a system comprising a liquid dispenser and a bay.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDxTM WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “Liquid Handling Processing A: Lysis and Capture. Dispensing lysis buffer. Dispensing lysis buffer and patient specimen into extraction plate. The liquid handling robot delivers lysis buffer and patient specimen to the extraction plate, which has 24 independent wells which contain


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	system comprising a liquid dispenser and a bay,	<p>NeuDry affinity-coated paramagnetic beads. Each mixture is aspirated and dispensed five times to ensure homogeneity of the solution. During the transfer of patient specimen to the extraction plate the liquid handling robot uses pre-defined no-fly zones to reduce the potential of contamination.” <i>Id.</i> at 0:28-1:05</p> <ul style="list-style-type: none"> • <i>Id.</i> at 0:40 (showing the extraction plate).  <p>Downloaded on 3/26/2019</p> <ul style="list-style-type: none"> • “Liquid Handling Processing B: Extraction. After thoroughly mixing the solution in each well of the extraction plate, the crude lysate is independently aspirated from each well and transferred to the NeuMoDx cartridge.” <i>Id.</i> at 1:35-1:51. • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59



Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none"> • “The liquid handling robot employs total aspiration and dispense monitoring pressure sensing to ensure each tip is securely seated into one of the 12 independent sample ports or s-ports of the cartridge. Once the pipette tip is secured, the entire volume of solution will be dispensed.” <i>Id.</i> 2:02-2:24. • “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” <i>Id.</i> at 2:28-2:39. • <i>Id.</i> at 2:28 (showing liquid handling robot at the s-port and lysate in the s-channel).


Claim	Claim Language	Infringement Evidence
		<div data-bbox="659 228 1619 769"> </div> <ul style="list-style-type: none"> • “A precise volume of air is then applied to remove any remaining liquid into the waste chamber. NeuMoDx wash solution is pumped via the fluid port into the microfluidic cartridge to remove all unbound material, followed by another volume of air to remove excess wash solution. High pH NeuMoDx release reagent is dispensed into the s-channel to cover the beads, and heat is applied to the denaturation process, resulting in released nucleic acid or eluate.” <i>Id.</i> at 2:39-3:12. • <i>Id.</i> at 2:43-3:00 (showing dispensing of the wash solution and release solution) <div data-bbox="701 1029 1142 1330"> </div> <div data-bbox="1226 1029 1667 1330"> </div> <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> <li data-bbox="615 237 1892 378">• “The liquid handling robot aspirates the PCR-ready solution and transfers it back to the cartridge where it dispenses into the same p-port from which the sample was aspirated. A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:57-4:08. <li data-bbox="615 378 1423 415">• <i>Id.</i> at 3:57 (showing the liquid handling robot at the p-port).  <ul style="list-style-type: none"> <li data-bbox="615 943 1312 979">• <i>Id.</i> at 4:08 (showing the three thin PCR chambers).

Claim	Claim Language	Infringement Evidence
		<div data-bbox="661 228 1593 751">A microscopic image of a circuit board. It shows a dark grey substrate with white conductive traces. Several red rectangular components are mounted on the board. To the right, there are white, rectangular components that look like connectors or sensors. The image is taken at an angle, showing the perspective of the board's surface.</div> <p><i>NeuMoDx Molecular N288 System</i>, http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ TECHNOLOGY” hyperlink at https://player.vimeo.com/video/281470603. (Exhibit 17)</p> <ul style="list-style-type: none">• At 3:10 (showing a liquid dispenser)

Claim	Claim Language	Infringement Evidence
		 <p>Downloaded on 3/26/2019</p> <ul style="list-style-type: none">• At 4:17 (showing a plurality of multi-lane microfluidic cartridges in a plurality of receiving bays)

Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none">• at 4:55-5:00 (showing a plurality of multi-lane microfluidic cartridges in a plurality of receiving bays) 

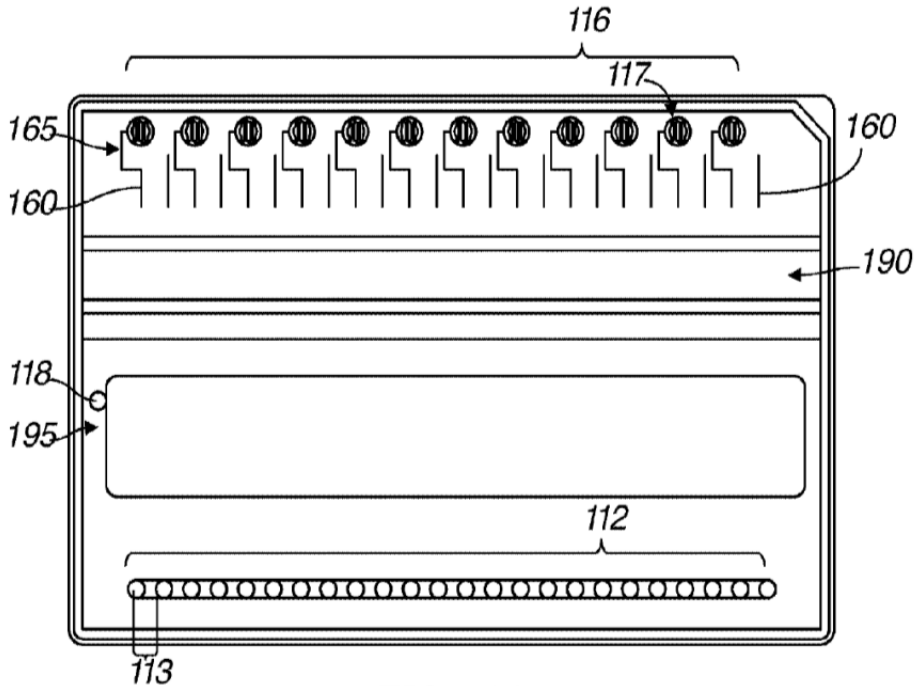
Claim	Claim Language	Infringement Evidence										
		<div></div> <p>“Patents”, http://www.neumodx.com/patents/ (Exhibit 47) demonstrating that NeuMoDx marks its products with US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; 9,452,430; 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; 10,010,888; 9,382,532; 9,540,636; 9,499,896; 10,239,060; 9,539,576; 10,226,771, 9,637,775; and 10,093,963</p> <h2>PATENTS</h2> <table><tr><th>Product</th><th>Patents</th></tr><tr><td>CARTRIDGE</td><td>US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.</td></tr><tr><td>P02 (overall system and method)</td><td>US Patent Nos. 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; and 10,010,888. CN Patent No. 201380009286.3.</td></tr><tr><td>EXTRACTION PLATE</td><td>US Patent Nos. 9,382,532; and 9,540,636. DE Patent No. 60 2013 056 932.0. DK Patent No. 2912174. EP Patent No. EP-B-2912174. ES Patent No. 300330453. FR Patent No. 2912174. GB Patent No. 2912174. IT Patent No. 502019000064944. NO Patent No. 2912174. SE Patent No. 2912174.</td></tr><tr><td>XPCR MODULE</td><td>US Patent Nos. 9,499,896; 10,239,060; 9,539,576; 10,226,771; 9,637,775; 10,093,963; 9,604,213; and 10,010,888.</td></tr></table>	Product	Patents	CARTRIDGE	US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.	P02 (overall system and method)	US Patent Nos. 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; and 10,010,888. CN Patent No. 201380009286.3.	EXTRACTION PLATE	US Patent Nos. 9,382,532; and 9,540,636. DE Patent No. 60 2013 056 932.0. DK Patent No. 2912174. EP Patent No. EP-B-2912174. ES Patent No. 300330453. FR Patent No. 2912174. GB Patent No. 2912174. IT Patent No. 502019000064944. NO Patent No. 2912174. SE Patent No. 2912174.	XPCR MODULE	US Patent Nos. 9,499,896; 10,239,060; 9,539,576; 10,226,771; 9,637,775; 10,093,963; 9,604,213; and 10,010,888.
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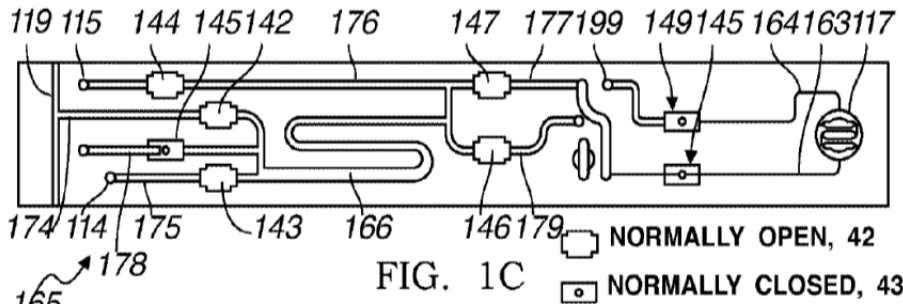
Claim	Claim Language	Infringement Evidence
		<p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> • Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10. • Claim 10. The method of claim 3, wherein washing the set of moiety-bound nucleic acid particles comprises aspirating the moiety-sample mixture; receiving the cartridge at the cartridge receiving module comprising the set of pins and a cam card interfacing with the set of pins; transitioning the cartridge to an active configuration that disposes the cartridge proximal the set of pins; displacing the first subset of the set of pins in the active configuration of the cartridge, upon translation of the cam card relative to the set of pins, thereby occluding the fluidic pathway of the cartridge at a set of occlusion positions; delivering the moiety-sample mixture into the fluidic pathway, wherein the fluidic pathway is configured to pass through a magnetic field and is coupled to a waste chamber, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field; and delivering a wash solution through the fluidic pathway and into the waste chamber in a continuous flow operation. • Claim 16. The method of claim 1, further comprising processing the nucleic acid sample, wherein processing the nucleic acid sample comprises modulating the fluidic pathway of the cartridge upon

Claim	Claim Language	Infringement Evidence
		<p>displacement of a third subset of the set of pins, thereby defining a path to a diagnostic chamber of the cartridge, delivering the nucleic acid sample to the diagnostic chamber, and amplifying nucleic acids of the nucleic acid sample within the diagnostic chamber by polymerase chain reaction.</p> <ul style="list-style-type: none"> <p>Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second subset of the set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction.</p> <p>Claim 19. A method for nucleic acid isolation from a biological sample, comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution includes a set of affinity moiety-coated microparticles, comprising a set of microparticles amide-bonded to at least one of Poly(allylamine) of molecular weight <30,000 Da and Polypropylenimine tetramine dendrimer Generation 1; producing a moiety-sample mixture upon combination of the binding moiety solution with the biological sample; producing a set of moiety-bound nucleic acid particles upon incubation of the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable</p>

Claim	Claim Language	Infringement Evidence
		<p>between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of the set of pins includes reversing displacement of at least one pin of the first subset of the set of pins, and reversing occlusion of a portion of the fluidic pathway.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at Abstract (“A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber; mixing the binding moiety solution with a biological sample, within the process chamber, in order to produce a moiety-sample mixture; incubating the moiety-sample mixture during a time window, thereby producing a solution comprising a set of moiety-bound nucleic acid particles and a waste volume; separating the set of moiety-bound nucleic acid particles from the waste volume; washing the set of moiety-bound nucleic acid particles; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles.”) • U.S. Patent No. 9,382,532 at 7:14-28 (“In Step S140, the lysed moiety-sample solution can be processed within the process chamber to separate the moiety-bound nucleic acid volume from the waste volume; however, the lysed moiety-sample solution can alternatively be transferred to another suitable vessel for separation of the moiety-bound nucleic acid volume from the waste volume. In a first variation, a pipetting system (automatic or manual) can be used to remove the waste volume (e.g., supernatant liquid), and multiple aspirations by the pipetting system may be necessary to ensure as complete a removal of the supernatant as possible. In an example of the first variation, a 1000 micro liter pipette tip can be used to perform gross removal of the waste volume in a first aspiration followed by the use of a finer pipette tip (e.g., 100-200 microliter tip) in additional aspirations, to remove the remainder of the waste volume.”) • U.S. Patent No. 9,382,532 at 10:58-63. (“As shown in FIGS. 1A, 1B, and 2, the method 100 can further comprise Step S170, which recites processing the nucleic acid sample. Processing can comprise amplifying the nucleic acid(s) of the nucleic acid sample (e.g., by polymerase chain reaction), or any other suitable method for processing nucleic acids.”) • Patent No. 9,382,532 at 23:23-28 (“In a specific example, the valve actuation subsystem 170

Claim	Claim Language	Infringement Evidence
		<p>comprises 12 sets of pins 172 configured to selectively occlude 12 fluidic pathways 212 of a microfluidic cartridge 210 aligned within the molecular diagnostic module; however, other embodiments may comprise any appropriate number of sets of pins 172.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,382,532 at 24:14-22 (“The first illustration of the fluidic pathway 165 also comprises a reagent segment 176 coupled to a reagent port 115 and to the capture segment 166, a vent segment 177 coupled to the reagent segment 176 and configured to pass through the vent region 190, a segment running to a detection chamber 163 from the vent region 190, a winding segment running away from the detection chamber 164, and an end vent 199 coupled to the segment running away from the detection chamber 164.”) <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position of the fluidic pathway, by way of the void of the corrugated surface, the fluidic pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber. Claim 2. The cartridge of claim 1, wherein the first layer is a unitary construction comprising a reagent port, the fluid port, and a detection chamber, and wherein the fluidic pathway is coupled to the reagent port, the fluid port, and the detection chamber. Claim 4. The cartridge of claim 3, wherein the fluidic pathway comprises a capture segment, downstream of the sample port and configured to cross the magnet housing region multiple times. Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a

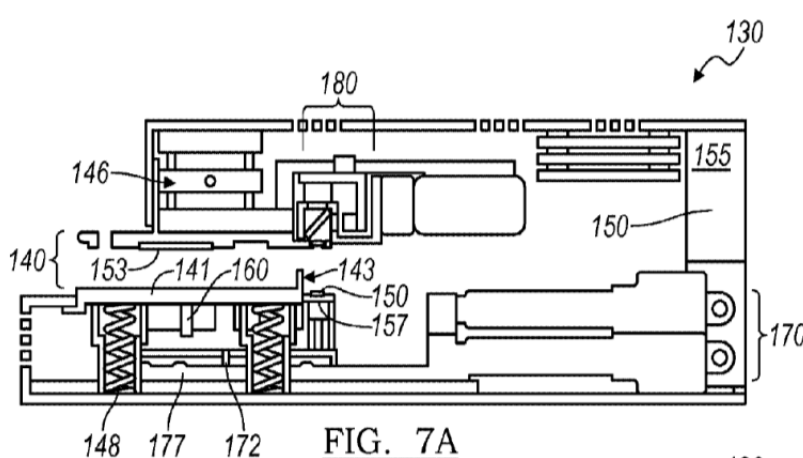
Claim	Claim Language	Infringement Evidence
		<p>portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate.</p> <ul style="list-style-type: none"> • Claim 10. The cartridge of claim 8, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the second detection chamber, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port. • U.S. Patent No. 9,403,165 at 1A.  <p style="text-align: center;">FIG. 1A</p>

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> <p data-bbox="617 238 1157 264">U.S. Patent No. 9,403,165 at FIG. 1C .</p> <div data-bbox="680 289 1577 591">  <p data-bbox="1052 548 1199 574">FIG. 1C</p> </div> <p data-bbox="617 626 1913 912">U.S. Patent No. 9,403,165 at 3:32-43 (“Each sample-port-reagent port pair 113 of an embodiment of the top layer 110 comprises a sample port 114 and a reagent port 115. The sample port 114 functions to receive a volume of a sample fluid potentially containing the nucleic acids of interest for delivery of the volume of fluid to a portion of a fluidic pathway 165 coupled to the sample port-reagent port pair 113. In a specific embodiment, the volume of a sample fluid is a biological sample with magnetic beads for nucleic acid isolation; however, the volume of fluid comprising a sample fluid may alternatively be any appropriate fluid containing a sample with nucleic acids.”)</p> <p data-bbox="617 922 1913 1279">U.S. Patent No. 9,403,165 at 3:53-67 (“Each sample-port reagent port pair 113 of an embodiment of the top layer 110 also comprises a reagent port 115, as shown in FIG. 1A. The reagent port 115 in a sample port-reagent port pair 113 functions to receive a volume of fluid comprising a reagent used in molecular diagnostics, for delivery of the volume of fluid comprising a reagent to a portion of a fluidic pathway 165 coupled to the sample port-reagent port pair 113. In a specific embodiment, the volume of fluid comprising a reagent used in molecular diagnostics is a sample of reconstituted molecular diagnostic reagents mixed with nucleic acids released and isolated using the microfluidic cartridge 100; however, the volume of fluid comprising a reagent used in molecular diagnostics may alternatively be any appropriate fluid comprising reagents used in molecular diagnostics.”)</p> <p data-bbox="617 1289 1913 1386">U.S. Patent No. 9,403,165 at 7:66-8:6 (“The top layer 110 of the microfluidic cartridge 100 may further comprise a set of cartridge-aligning indentations 180, which function to align the microfluidic cartridge 100 as it moves through an external module.”)</p>

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at 13:23-30 (“The set of fluidic pathways 160 of the microfluidic cartridge 100 functions to provide a fluid network into which volumes of sample fluids, reagents, buffers and/or gases used in a molecular diagnostics protocol may be delivered, out of which waste fluids may be eliminated, and by which processed nucleic acid samples may be delivered to a detection chamber for analysis, which may include amplification and/ or detection.”) U.S. Patent No. 9,403,165 at 14:65-15:2 (“The capture segment 166 functions to facilitate isolation and purification of nucleic acids from the volume of the sample fluid, and may be s-shaped and/or progressively narrowing, to increase the efficiency and/or effectiveness of isolation and purification.”) U.S. Patent No. 9,403,165 at 17:17-33 (“Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”) U.S. Patent No. 9,403,165 at 21:33-40 (“Additionally, the set of fluidic pathways 160 of the microfluidic cartridge 100 may comprise virtually any number of fluidic pathway 165 and/or the set of Detection chambers 116 may comprise virtually any number of Detection chambers 116 as can practically be integrated into the microfluidic cartridge 100. In one specific embodiment, the set of fluidic pathways 160 may comprise twelve fluidic pathways 165, four of which are shown in FIG. 9.”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate,

Claim	Claim Language	Infringement Evidence
		<p>and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • Claim 2. The system of claim 1, further comprising a liquid handling system configured to transfer at least one magnetic bead-sample from the capture plate to the molecular diagnostic module, and to aspirate at least one nucleic acid volume from the molecular diagnostic module. • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to

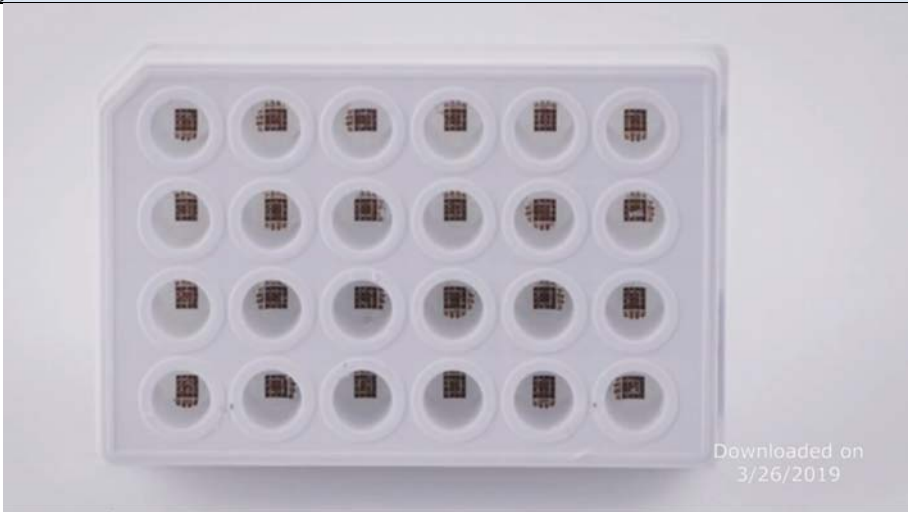
Claim	Claim Language	Infringement Evidence
		<p>the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 23. A system for processing and detecting nucleic acids, comprising: a molecular diagnostic module, configured to process a set of biological samples combined with magnetic beads and separate a set of nucleic acid volumes from the set of biological samples combined with magnetic beads, wherein the molecular diagnostic module comprises an actuator configured to displace a cartridge, a set of pins, and at least one cam contacting the set of pins, wherein an extension or retraction of the actuator moves the cartridge, and a displacement of a subset of the set of pins defines a set of pathways in the cartridge, each configured to receive a biological sample combined with magnetic beads of the set of biological samples combined with magnetic beads. • Claim 24. The system of claim 23, further comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample, a lysing reagent, and a sample process control, wherein the capture plate facilitates production of at least one biological sample combined with magnetic beads; an assay strip comprising at least one reagent well containing a molecular diagnostic reagent volume configured to be combined with a nucleic acid volume of the set of nucleic acid volumes to produce at least one nucleic acid-reagent mixture; and a liquid handling system configured to transfer at least one biological sample combined with magnetic beads from the capture plate to the molecular diagnostic module, transfer at least one nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer at least one nucleic acid-reagent mixture from the assay strip back to the molecular diagnostic module. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine

Claim	Claim Language	Infringement Evidence
		<p>nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 2:49-3:6 (“As shown in FIGS. 1A-1B and 7A, an embodiment of a system 100 for processing and detecting nucleic acids comprises: a capture plate 110 configured to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119; a molecular diagnostic module 130 comprising a microfluidic cartridge receiving module 140, heating and cooling subsystem 150, a magnet 160, a valve actuation subsystem 170, an optical subsystem 180; and an assay strip 190 configured to facilitate mixing of molecular diagnostic reagents with a nucleic acid volume. Other embodiments of the system 100 may further comprise at least one of a capture plate module 120 configured to support the capture plate 110; a filter 200 and filter holder 205 to facilitate sample preparation; a microfluidic cartridge 210 configured to facilitate sample processing; an assay strip holder 230; an assay strip carrier 240; a liquid handling system 250 configured to facilitate gas and fluid delivery to different elements of the system 100; a processor configured to analyze data resulting from a run of the system 100; and a user interface configured to allow a user to interact with the system 100. The system 100 thus functions to receive biological samples containing nucleic acids (i.e., impure nucleic acid samples), separate nucleic acids from the biological samples, and analyze nucleic acid samples according to at least one molecular diagnostic protocol (e.g., PCR).”) U.S. Patent No. 9,050,594 at FIG. 7A  <p style="text-align: center;">FIG. 7A</p>

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 9:32-41 (“Additionally, the extended configuration 146b of the scissor jack actuator is configured to couple the nozzle 149 to a fluid port 222 of the microfluidic cartridge 210, such that the liquid handling system 250 can deliver solutions and gases for processing of biological samples. The linear actuator 146 may alternatively be any appropriate linear actuator, such as a hydraulic, pneumatic, or motor-driven linear actuator, configured to linearly displace a microfluidic cartridge within the molecular diagnostic module 130.”) • U.S. Patent No. 9,050,594 at 22:29-33 (“The microfluidic cartridge 210 functions to receive a set of magnetic bead-samples, facilitate separation of nucleic acids from the set of magnetic bead-samples, receive a set of nucleic acid-reagent samples, and facilitate analysis of nucleic acids from the set of nucleic acid-reagent samples.”) • U.S. Patent No. 9,050,594 at 23:28-58 (“The liquid handling system 250 of the system 100 includes a liquid handling arm 255 and a syringe pump 265, as shown in FIGS. 14A-14C and functions to deliver biological samples, reagents, and gases to elements of the system 100. As described in Section 1, an embodiment of the liquid handling system 250 is configured to aspirate a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), dispense the set of biological samples into a capture plate no to be lysed and combined with magnetic beads by a capture plate module 120, aspirate the set of biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate 110, and dispense the set of magnetic bead-samples into microfluidic cartridge 210 located in a molecular diagnostic module 130. The embodiment of the liquid handling system 100 is further configured to facilitate separation of a set of nucleic acids from the magnetic bead-samples, by dispensing a wash solution, a release solution, and/or air into the molecular diagnostic module 130, by the nozzle 149 coupled to the linear actuator 146, at appropriate stages, aspirate the set of nucleic acids from the molecular diagnostic module 130, combine the set of nucleic acids with a set of molecular diagnostic reagents using an assay strip 190, and dispense the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the molecular diagnostic module 130 for further processing and analysis. [Other embodiments of the liquid handling system 250 may be configured to perform alternative molecular diagnostic assay protocols and/or dispense and aspirate alternative fluids into and from other elements supporting a molecular diagnostic protocol.”) • U.S. Patent No. 9,050,594 at FIG. 14B.

Claim	Claim Language	Infringement Evidence
		<div data-bbox="667 284 1501 844" data-label="Image"> <p>FIG. 14B</p> </div> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 24:16-18 (“The multichannel liquid handling head 257 functions to aspirate fluids from and deliver fluids to different elements of the system 100.”) • U.S. Patent No. 9,050,594 at 27:2-26 (“An embodiment of a method 400 for processing and detecting nucleic acids from a set of biological samples comprises: combining each biological sample of the set of biological samples with a quantity of magnetic beads to produce a set of magnetic bead-sample mixtures S410; heating the set of magnetic bead-sample mixtures to produce a set of nucleic acid-magnetic bead samples S420; transferring each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways S430; producing a set of nucleic acid volumes from the set of nucleic acid-magnetic bead samples S440; combining each nucleic acid volume of the set of nucleic acid volumes with a molecular diagnostic reagent of a set of molecular diagnostic reagents to produce a set of nucleic acid-reagent mixtures S450; transferring each of the set of nucleic acid-reagent mixtures, through the corresponding fluidic pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers S460; and

Claim	Claim Language	Infringement Evidence
		<p>receiving light from the set of nucleic acid-reagent mixtures S470. The method 400 may farther comprise generating a set of data based on light received form the set of nucleic acid-reagent mixtures S480. The method 400 functions to isolate and extract a set of nucleic acid volumes from a biological sample, and to facilitate analysis of the nucleic acid volumes according to at least one molecular diagnostic protocol")</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 29:27-30 ("Step S440 recites producing a set of nucleic acid volumes from the set of nucleic acid-magnetic bead samples, and functions to separate nucleic acid volumes from the set of nucleic acid-magnetic bead samples.") • U.S. Patent No. 9,050,594 at 31:32-37 ("Step S460 recites transferring each of the set of nucleic acid-reagent mixtures, through the corresponding fluidic pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers, which functions to deliver the set of nucleic acid-reagent mixtures to an isolated detection chamber for further processing and analysis.")
1(c)	the first module comprising a magnetic separator and a heating assembly,	<p>In the accused workflow the first module comprises a magnetic separator and a heating assembly.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to "VIDEO NeuMoDx™ WORKFLOW" hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • "Liquid Handling Processing A: Lysis and Capture. Dispensing lysis buffer. Dispensing lysis buffer and patient specimen into extraction plate. The liquid handling robot delivers lysis buffer and patient specimen to the extraction plate, which has 24 independent wells which contain NeuDry affinity-coated paramagnetic beads. Each mixture is aspirated and dispensed five times to ensure homogeneity of the solution. During the transfer of patient specimen to the extraction plate the liquid handling robot uses pre-defined no-fly zones to reduce the potential of contamination." <i>Id.</i> at 0:28-1:05 • <i>Id.</i> at 0:40 (showing the extraction plate).

Claim	Claim Language	Infringement Evidence
		<div data-bbox="661 228 1562 737">A photograph of a white, rectangular microfluidic device with a 4x6 grid of circular channels. Each channel contains a small, dark, square component, likely a valve or magnet. The device is shown against a light background. A watermark in the bottom right corner of the image reads "Downloaded on 3/26/2019".</div> <ul style="list-style-type: none">• “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” <i>Id.</i> at 2:28-2:39.• <i>Id.</i> at 2:28 (showing lysate in the s-channel).

Claim	Claim Language	Infringement Evidence
		<div data-bbox="659 228 1619 769" data-label="Image"> </div> <ul style="list-style-type: none"> • “A precise volume of air is then applied to remove any remaining liquid into the waste chamber. NeuMoDx wash solution is pumped via the fluid port into the microfluidic cartridge to remove all unbound material, followed by another volume of air to remove excess wash solution. High pH NeuMoDx release reagent is dispensed into the s-channel to cover the beads, and heat is applied to the denaturation process, resulting in released nucleic acid or eluate.” <i>Id.</i> at 2:39-3:12. <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> • Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the

Claim	Claim Language	Infringement Evidence
		<p>cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 5. The method of claim 3, wherein separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture. • Claim 6. The method of claim 5, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety-sample mixture from the process chamber; occluding the fluidic pathway of the cartridge-at a set of occlusion positions upon displacement of pins of the set of pins to generate a path through a magnetic field, and to a waste chamber; and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber. • Claim 10. The method of claim 3, wherein washing the set of moiety-bound nucleic acid particles comprises aspirating the moiety-sample mixture; receiving the cartridge at the cartridge receiving module comprising the set of pins and a cam card interfacing with the set of pins; transitioning the cartridge to an active configuration that disposes the cartridge proximal the set of pins; displacing the first subset of the set of pins in the active configuration of the cartridge, upon translation of the cam card relative to the set of pins, thereby occluding the fluidic pathway of the cartridge at a set of occlusion positions; delivering the moiety-sample mixture into the fluidic pathway, wherein the fluidic pathway is configured to pass through a magnetic field and is coupled to a waste chamber, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field; and delivering a wash solution through the fluidic pathway and into the waste chamber in a continuous flow operation.. • Claim 14. The method of claim 13, further comprising capturing the set of moiety-bound nucleic acid particles within the magnetic field and aspirating the nucleic acid sample from the

Claim	Claim Language	Infringement Evidence
		<p>fluidic pathway.</p> <ul style="list-style-type: none"> Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second subset of the set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction. Claim 18. The method of claim 17, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety-sample mixture from the process chamber; occluding the fluidic pathway of the cartridge at a set of occlusion positions upon displacement of the first subset of the set of pins to generate a path through a magnetic field, and to a waste chamber of the cartridge; and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber. Patent No. 9,382,532 at 4:35-44 (“In a specific example of this variation of Step S110, the microparticles are magnetic beads (e.g., magnetic, paramagnetic [sic], superparamagnetic) with any suitable hydrophilicity (e.g., hydrophobic, hydrophilic), wherein the magnetic beads are coated with the affinity moiety and simultaneously received within the process chamber along

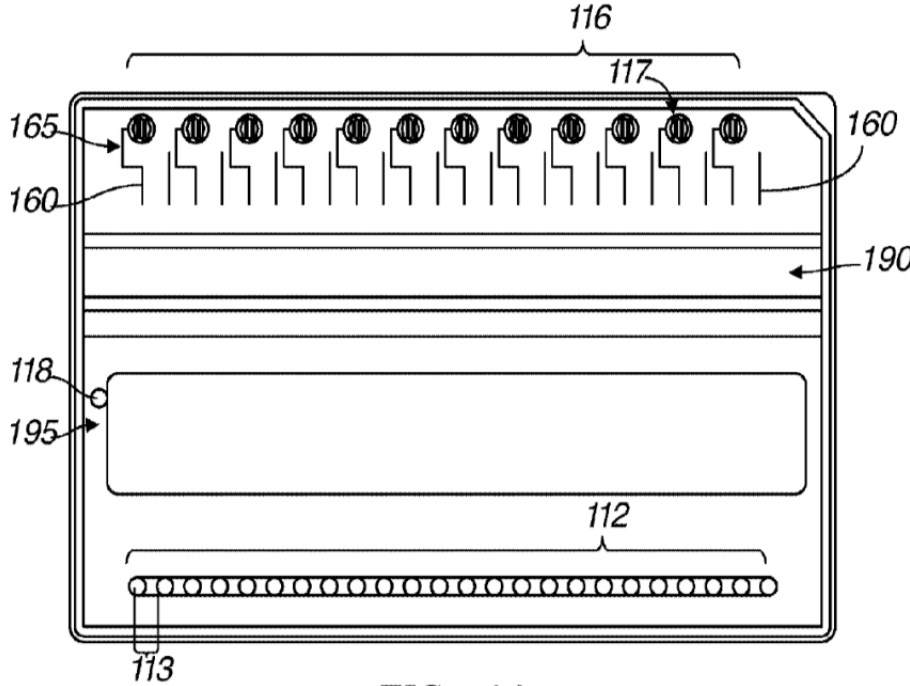
Claim	Claim Language	Infringement Evidence
		<p>with a low-pH buffer solution, proteolytic enzymes, and lytic reagents. In this specific example, magnetic separation can be used to facilitate further processing and isolation of nucleic acids bound to the affinity moieties coupled to magnetic beads.")</p> <ul style="list-style-type: none"> • Patent No. 9,382,532 at 8:5-10 ("Furthermore, the microparticles of the moiety-bound nucleic acid volume can be agitated to go back into a suspension from a compacted state (e.g., during magnetic capture) or the wash solution can simply be flowed over the microparticles to further remove non- specific moieties and facilitate exchange of buffers.") • Patent No. 9,382,532 at 8:41-55 ("In a variation of the first example of Step S150, a system (such as the one described in U.S. patent application Ser. No. 13/766,359, entitled "System and Method for Processing and Detecting Nucleic Acids") can be used to deliver the wash solution into a fluidic pathway of a cartridge (such as the one described in U.S. patent application Ser. No. 13/765,996, entitled "Microfluidic Cartridge for Processing and Detecting Nucleic Acids"). In the variation of the first example, the microparticles of the moiety-bound nucleic acid volume can be retained by a magnetic field within a portion of the fluidic pathway upon occlusion of the fluidic pathway at a suitable set of occlusion positions, and the wash solution can be delivered through the portion of the fluidic pathway and into a waste chamber of the cartridge to wash the microparticles with the bound target nucleic acid(s).") • Patent No. 9,382,532 at 9:63-10:13 ("In a specific example of Steps S160 and S161, a system (such as the one described in U.S. patent application Ser. No. 13/766,359, entitled "System and Method for Processing and Detecting Nucleic Acids") can be used to deliver the elution solution into a fluidic pathway of a cartridge (such as the one described in U.S. patent application Ser. No. 13/765,996, entitled "Microfluidic Cartridge for Processing and Detecting Nucleic Acids"). In the variation of the specific example, the microparticles of the moiety-bound nucleic acid volume can be retained by a magnetic field within a portion of the fluidic pathway upon occlusion of the fluidic pathway at a suitable set of occlusion positions, and the elution solution can be delivered through the portion of the fluidic pathway enable release of the nucleic acid sample from the microparticle.") • Patent No. 9,382,532 at 9:31-62 (" In some variations, Step S160 can further comprise Step S161, which recites heating the moiety-bound nucleic acid volume. Step S161 functions to provide additional environmental conditions that facilitate release of the nucleic acid sample from the microparticles, and can further function to mitigate effects of proteolytic enzymes that are used in Steps S110, S120, and/or S130 or that may be released from the biological sample containing the

Claim	Claim Language	Infringement Evidence
		<p>nucleic acid. Preferably, an elevated temperature in combination with an elevated pH resulting from the elution solution provides the enhanced conditions to facilitate the release of the nucleic acid sample. Furthermore, an elevated temperature (e.g., elevating a sample eluted at room temperature to 85 C) can function to minimize protease enzyme activity in the eluted nucleic acid and thereby improve the robustness of the detection of the target nucleic acid sample during processing in variations of Step S110; however, the method 100 can alternatively omit Step S161 in applications wherein heating the moiety-bound nucleic acid volume is undesirable and/or unnecessary. Furthermore, variations of Step S161 can comprise heating at higher temperatures for shorter time periods, or heating at lower temperatures for longer time periods. In an example of Step S161, heating comprises elevating the temperature of the moiety-bound nucleic acid volume to 80-85 C, for 3 minutes, and in another example, heating comprises elevating the temperature of the moiety-bound nucleic acid volume to 50-70 C, for 3-10 minutes. In other examples, the elevation temperature can be maintained at a desired set-point for as low as 1 minute or as high as 30 minutes. Further, elution conditions may be optimized to ensure that the bound nucleic acid is only eluted in the presence of the high pH solution at the elevated temperature for a specified amount of time.”)</p> <ul style="list-style-type: none"> • Patent No. 9,382,532 at 10:46-57 (“In specific examples, however, Step S165 can comprise any combination of: not washing the moiety-bound nucleic acid volume, passively washing the moiety-bound nucleic acid volume, not removing a wash solution from the moiety-bound nucleic acid volume, washing the moiety-bound nucleic acid volume with a Tris solution (e.g., 1 mM Tris solution), eluting the nucleic acid sample at room temperature, eluting the nucleic acid sample at 99 C, eluting the nucleic acid sample at 55 C, and not resuspending moiety-bound microparticles in a release buffer, any combination of which can affect amplification of the nucleic acids or the process control.”) • Patent No. 9,382,532 at 11:6-23 (“In a specific example of this variation, a system (such as the one described in U.S. patent application Ser. No. 13/766,359, entitled "System and Method for Processing and Detecting Nucleic Acids") can be used to aspirate the nucleic acid sample from a fluidic path way of a cartridge (such as the one described in U.S. patent application Ser. No. 13/765,996, entitled "Microfluidic Cartridge for Processing and Detecting Nucleic Acids"), while the microparticles are immobilized by a magnet. The system can then combine the nucleic acid sample with process reagents (e.g., PCR reagents) in a separate container (e.g., assay plate), and then transfer the nucleic acid sample combined with process reagents to a detection chamber of the

Claim	Claim Language	Infringement Evidence
		<p>fluidic pathway (upon occlusion and/or opening of the fluidic channel at another subset of occlusion positions). The nucleic acid sample combined with process reagents can then be processed within a diagnostic chamber that is coupled to the fluidic pathway.”)</p> <ul style="list-style-type: none"> • Patent No. 9,382,532 at 12:51-56 (“The affinity moieties, such as the PAA and DABAM described in Section 2.1 and 2.2, can be immobilized on a suitable substrate to facilitate subsequent capture of target nucleic acids bound to the substrate (e.g., by magnetic separation, size-based separation, density-based separation, or focusing.)”) • Patent No. 9,382,532 at 13:7-9 (“The method 200 functions to produce a set of moiety-bound microparticles for nucleic acid isolation.”) • Patent No. 9,382,532 at 13:14-28 (“In a specific example, as shown in FIG. 3, the method 200 comprises activating magnetic carboxylated microparticles with EDAC in Step S110 to form a set of magnetic microparticle-reactive ester compounds; treating the set of magnetic microparticle-reactive ester compounds with a N-Hydroxysulfosuccinimide to form a set of microparticle-amine reactive ester compounds S220; combining the set of microparticle-amine reactive ester compounds with a set of affinity moieties selected from the group comprising PAA of molecular weight less than 30,000 Da and DABAM of generation less than two S230 to produce a microparticle-moiety solution; and repeatedly washing the microparticle-moiety solution, thereby producing a set of magnetic microparticles covalently bonded to the set of affinity moieties by amide bonds S240.”) • Patent No. 9,382,532 at 13:42-60 (“A first example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, cerebrospinal fluid (CSF) as a representative biological sample, and Enterovirus (EV) viral particles as the model target. In the first example, 200 μL of CSF was spiked with 2 μL of EV viral particle lysate and then mixed with 500 μL of RNA Collection Buffer 1 (CBR-1) and 300 μL of nuclease-free water in examples of Steps S110 and S120. As a comparison, a similar amount of EV particle lysate was spiked into a 1 mL solution comprised of 500 μL of CBR-1 buffer and 500 μL of nuclease-free water and processed simultaneously. In an example of Step S130, RNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 60 C. Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2\times) with 500 μL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) <i>See also id.</i> at 14:5-23, 14:41-59, 15:8-24, 15:58-16:12,

Claim	Claim Language	Infringement Evidence
		<p>16:29-44, 16:61-17:10, 17:27-43, 17:60-18:14, 18:31-47, 19:12-27, 19:46-61, 20:7-23, 20:33-50, 21:23-39, 21:58-22:8, 22:31-49.</p> <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> • Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position of the fluidic pathway, by way of the void of the corrugated surface, the fluidic pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber. • Claim 3. The cartridge of claim 1, wherein the waste chamber comprises at least one waste inlet in communication with the opening of the intermediate substrate, and wherein the corrugated surface of the waste chamber further defines a rectangular prismatic void spanning a long dimension of the cartridge that defines a magnet housing region configured to reversibly receive a magnet from the direction perpendicular to a broad face of the first layer, and configured to cross the fluidic pathway. • Claim 4. The cartridge of claim 3, wherein the fluidic pathway comprises a capture segment, downstream of the sample port and configured to cross the magnet housing region multiple times. • Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an

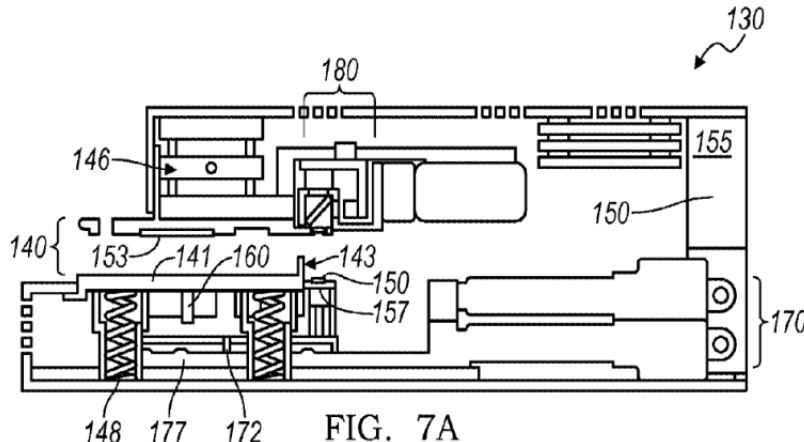
Claim	Claim Language	Infringement Evidence
		<p>elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate.</p> <ul style="list-style-type: none"> • Claim 10. The cartridge of claim 8, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the second detection chamber, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port. • Claim 11. The cartridge of claim 10, further comprising 1) a heating region defined as a recessed region of the first layer that is parallel to the set of voids of the corrugated surface, and 2) a vent region, such that the first fluidic pathway is configured to cross the heating region and to pass through the vent region upstream of the first detection chamber, and the second fluidic pathway is configured to cross the heating region and to pass through the vent region upstream of the second detection chamber. • Claim 15. The cartridge of claim 8, wherein at least one void of the set of voids defined by the corrugated surface of the waste chamber is a rectangular prismatic void spanning a long dimension of the cartridge and defining a magnet housing region configured to cross the first fluidic pathway and the second fluidic pathway. • U.S. Patent No. 9,403,165 at 2:39-63 (“As shown in FIGS. 1A-1C, an embodiment of a microfluidic cartridge 100 for processing and detecting nucleic acids comprises: a top layer 110 comprising a set of sample port-reagent port pairs 112 and a set of detection chambers 116; an intermediate substrate 120, coupled to the top layer 110 and partially separated from the top layer by a film layer 125, configured to form a waste chamber 130; an elastomeric layer 140 partially situated on the intermediate substrate 120; a magnet housing region 150 accessible by a magnet 152 providing a magnetic field 156; and a set of fluidic pathways 160, each formed by at least a portion of the top layer 110, a portion of the film layer 125, and a portion of the elastomeric layer 140. In other embodiments, the microfluidic cartridge 100 may further comprise a bottom layer 170 coupled to the intermediate substrate 120 and configured to seal the waste chamber 130. Furthermore, the top layer 110 of the microfluidic cartridge 100 may further comprise a shared fluid port 118, a vent region 190, and a heating region 195, such that each fluidic pathway 165 in the set of fluidic pathways 160 is fluidically coupled to a sample port-reagent port pair 113, the


Claim	Claim Language	Infringement Evidence
		<p>shared fluid port 118, the waste chamber 130, and a detection chamber 117, comprises a capture segment 166 configured to pass through the heating region and the magnetic field, and is configured to pass through the vent region 190 upstream of the detection chamber 117.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at 1A.  <p style="text-align: center;">FIG. 1A</p> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at FIG. 1C .


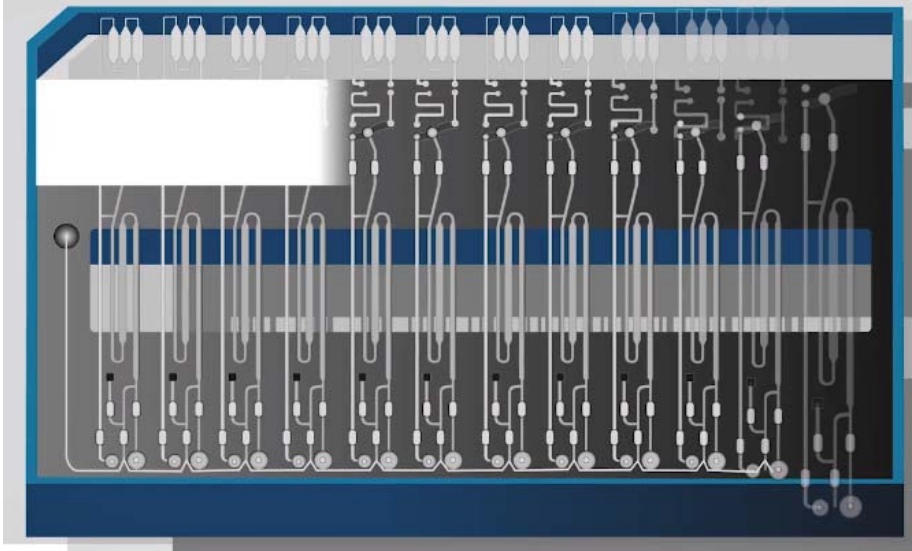
Claim	Claim Language	Infringement Evidence
		<div data-bbox="682 251 1585 560" data-label="Diagram"> </div> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at 12:38-52 (“The magnet housing region 150 of the microfluidic cartridge 100 functions to provide access to and/or house at least one magnet 152 providing a magnetic field 156 for purification and isolation of nucleic acids.... The magnet housing region 150 is preferably a rectangular prism-shaped void in the microfluidic cartridge 150, and accessible only through one side of the microfluidic cartridge 100, as shown in FIG. 1B.”) U.S. Patent No. 9,403,165 at 21:17-21 (“Multiple fluidic pathways may be configured to pass through a single heating region 195 of the microfluidic cartridge 100, a single vent region 190 of the microfluidic cartridge 100, and/or a magnetic field 156 produced by a magnet 152 housed within a single magnet housing region 150.”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.

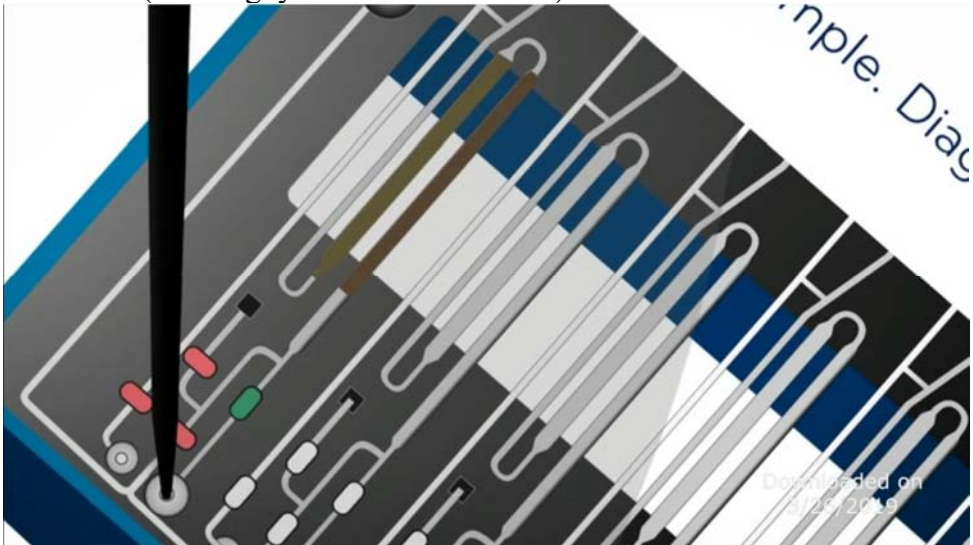
Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • Claim 8. The system of claim 1, wherein the magnet is configured to provide a magnetic field spanning at least three fluidic pathways configured to facilitate isolation and extraction of three nucleic acid volumes. • Claim 12. The system of claim 1, wherein the molecular diagnostic module further comprises a molecular diagnostic module heater configured to heat at least one magnetic bead-sample. • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module. • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater.

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • Claim 23. A system for processing and detecting nucleic acids, comprising: a molecular diagnostic module, configured to process a set of biological samples combined with magnetic beads and separate a set of nucleic acid volumes from the set of biological samples combined with magnetic beads, wherein the molecular diagnostic module comprises an actuator configured to displace a cartridge, a set of pins, and at least one cam contacting the set of pins, wherein an extension or retraction of the actuator moves the cartridge, and a displacement of a subset of the set of pins defines a set of pathways in the cartridge, each configured to receive a biological sample combined with magnetic beads of the set of biological samples combined with magnetic beads. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) • U.S. Patent No. 9,050,594 at 2:49-58 (“As shown in FIGS. 1A-1B and 7A, an embodiment of a system 100 for processing and detecting nucleic acids comprises: a capture plate 110 configured to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119; a molecular diagnostic module 130 comprising a microfluidic cartridge receiving module 140, heating and cooling subsystem 150, a magnet 160, a valve actuation subsystem 170, an optical subsystem 180; and an assay strip 190 configured to facilitate mixing of molecular diagnostic reagents with a nucleic acid volume.”) • U.S. Patent No. 9,050,594 at FIG. 7A

Claim	Claim Language	Infringement Evidence
		 <p style="text-align: center;">FIG. 7A</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 10:49-52 (“The cartridge heater 153 functions to transfer heat to a heating region 224 of a microfluidic cartridge 210, for inducing a pH shift to release bound nucleic acids from magnetic beads within the heating region 224.”) • U.S. Patent No. 9,050,594 at 12:64-13:1 (“The magnet 160 of the molecular diagnostic module 130 functions to provide a magnetic field for isolation and extraction of nucleic acids bound to magnetic beads within a microfluidic cartridge 210, aligned within the molecular diagnostic module 130.”)
1(d)	wherein extracting the nucleic acids comprises removably receiving a housing comprising a plurality of process chambers in the bay, the plurality of process chambers maintained at a same height relative to one another as the	<p>In the accused workflow extracting the nucleic acids comprises removably receiving a housing comprising a plurality of process chambers in the bay, the plurality of process chambers maintained at a same height relative to one another as the housing is received in and removed from the bay.</p> <p><i>NeuMoDx Molecular N288 System</i>, http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ TECHNOLOGY” hyperlink at https://player.vimeo.com/video/281470603. (Exhibit 17)</p> <ul style="list-style-type: none"> • At 4:17 (showing a plurality of multi-lane microfluidic cartridges in a plurality of receiving bays)

Claim	Claim Language	Infringement Evidence
	housing is received in and removed from the bay	<div data-bbox="564 228 1539 776"></div> <ul style="list-style-type: none">• at 4:55-5:00 (showing a plurality of multi-lane microfluidic cartridges in a plurality of receiving bays) <div data-bbox="564 852 1539 1330"></div>

Claim	Claim Language	Infringement Evidence
		<div data-bbox="569 233 1633 527">  </div> <p data-bbox="569 565 1923 672"><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul data-bbox="617 678 1871 781" style="list-style-type: none"> • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59 <div data-bbox="661 786 1566 1333">  </div> <ul data-bbox="617 1339 1896 1406" style="list-style-type: none"> • “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with

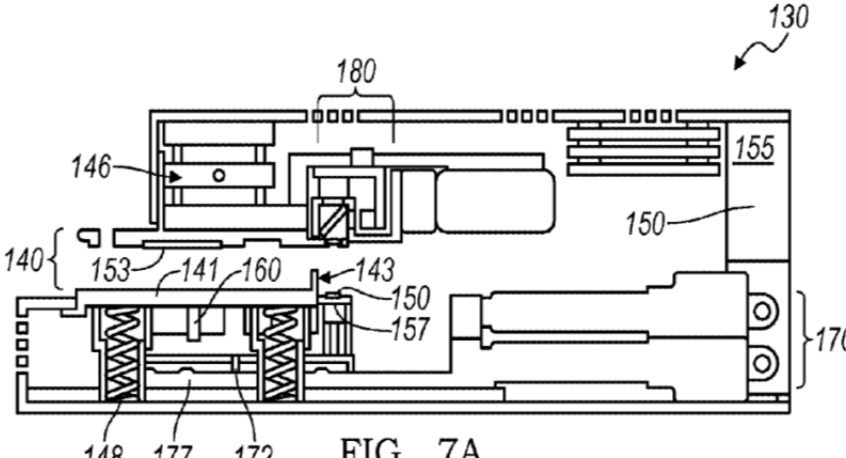
Claim	Claim Language	Infringement Evidence
		<p>the excess solution flowing into a self-contained waste chamber.” <i>Id.</i> at 2:28-2:39.</p> <ul style="list-style-type: none"> • <i>Id.</i> at 2:28 (showing lysate in the s-channel). “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” <i>Id.</i> at 2:28-2:39. • <i>Id.</i> at 2:28 (showing lysate in the s-channel).  <ul style="list-style-type: none"> • “A precise volume of air is then applied to remove any remaining liquid into the waste chamber. NeuMoDx wash solution is pumped via the fluid port into the microfluidic cartridge to remove all unbound material, followed by another volume of air to remove excess wash solution. High pH NeuMoDx release reagent is dispensed into the s-channel to cover the beads, and heat is applied to the denaturation process, resulting in released nucleic acid or eluate.” <i>Id.</i> at 2:39-3:12. <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> • Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a

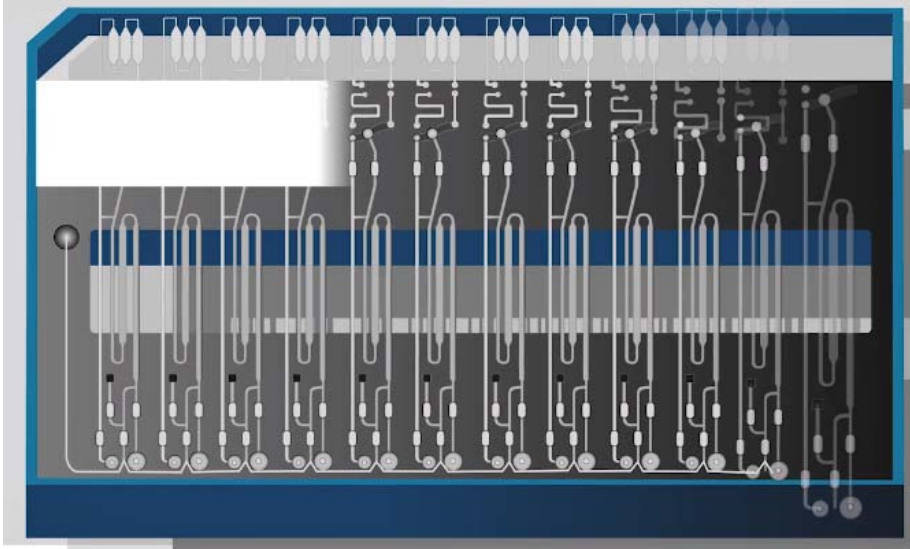
Claim	Claim Language	Infringement Evidence
		<p>set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 10. The method of claim 3, wherein washing the set of moiety-bound nucleic acid particles comprises aspirating the moiety-sample mixture; receiving the cartridge at the cartridge receiving module comprising the set of pins and a cam card interfacing with the set of pins; transitioning the cartridge to an active configuration that disposes the cartridge proximal the set of pins; displacing the first subset of the set of pins in the active configuration of the cartridge, upon translation of the cam card relative to the set of pins, thereby occluding the fluidic pathway of the cartridge at a set of occlusion positions; delivering the moiety-sample mixture into the fluidic pathway, wherein the fluidic pathway is configured to pass through a magnetic field and is coupled to a waste chamber, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field; and delivering a wash solution through the fluidic pathway and into the waste chamber in a continuous flow operation. • Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a

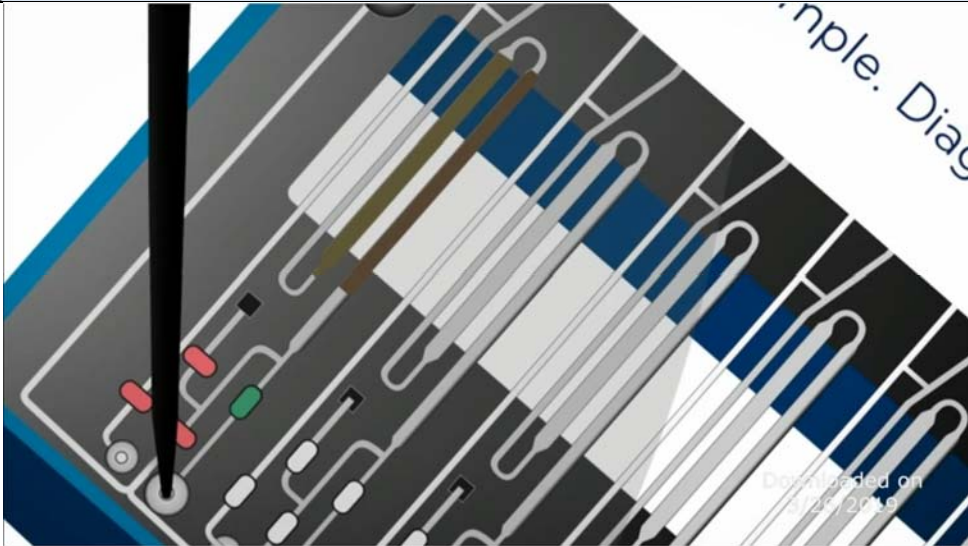
Claim	Claim Language	Infringement Evidence
		<p>moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second subset of the set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction.</p> <ul style="list-style-type: none"> • Claim 19. A method for nucleic acid isolation from a biological sample, comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution includes a set of affinity moiety-coated microparticles, comprising a set of microparticles amide-bonded to at least one of Poly(allylamine) of molecular weight <30,000 Da and Polypropylenimine tetramine dendrimer Generation 1; producing a moiety-sample mixture upon combination of the binding moiety solution with the biological sample; producing a set of moiety-bound nucleic acid particles upon incubation of the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of the set of pins includes reversing displacement of at least one pin of the first subset of the set of pins, and reversing occlusion of a portion of the fluidic pathway. • Patent No. 9,382,532 at 23:23-28 (“In a specific example, the valve actuation subsystem 170 comprises 12 sets of pins 172 configured to selectively occlude 12 fluidic pathways 212 of a microfluidic cartridge 210 aligned within the molecular diagnostic module; however, other

Claim	Claim Language	Infringement Evidence
		<p>embodiments may comprise any appropriate number of sets of pins 172.”)</p> <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> • Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position of the fluidic pathway, by way of the void of the corrugated surface, the fluidic pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber. • U.S. Patent No. 9,403,165 at 7:66-8:19. (“The top layer 110 of the microfluidic cartridge 100 may further comprise a set of cartridge-aligning indentations 180, which function to align the microfluidic cartridge 100 as it moves through an external module... Alternatively, the cartridge-aligning indentations may be grooves, such that the microfluidic cartridge 100 accurately slides into position along the grooves within a system external to the microfluidic cartridge 100. In yet another alternative embodiment, the set of cartridge-aligning indentations 180 may be any appropriate indentations that allow for positioning of the microfluidic cartridge 100 within an external system.”) • U.S. Patent No. 9,403,165 at 10:35-42 (“In an embodiment of the waste chamber 130 with a corrugated surface 137, at least two ridges of the corrugated surface 137 are preferably the same height, such that the microfluidic cartridge 100 sits substantially level on a flat base. In an alternative embodiment, all ridges of the corrugated surface 137 of the waste chamber 130 are identical, for structural symmetry, and in yet another embodiment, the waste chamber 130 may not have a corrugated surface 137.”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with

Claim	Claim Language	Infringement Evidence
		<p>a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) U.S. Patent No. 9,050,594 at 2:49-58 (“As shown in FIGS. 1A-1B and 7A, an embodiment of a system 100 for processing and detecting nucleic acids comprises: a capture plate 110 configured to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119; a molecular diagnostic module 130 comprising a microfluidic cartridge receiving module 140, heating and cooling subsystem 150, a magnet 160, a valve actuation subsystem 170, an optical subsystem 180; and an assay strip 190 configured to facilitate mixing of molecular diagnostic reagents with a nucleic acid volume.”) U.S. Patent No. 9,050,594 at 7A.  <p style="text-align: center;">FIG. 7A</p>

Claim	Claim Language	Infringement Evidence
1(e)	the plurality of process chambers aligned along a first axis when the housing is received in the bay	<p>In the accused workflow extracting the nucleic acids comprises removably receiving a housing comprising a plurality of process chambers in the bay, the plurality of process chambers maintained at a same height relative to one another as the housing is received in and removed from the bay, the plurality of process chambers aligned along a first axis when the housing is received in the bay.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59  <ul style="list-style-type: none"> • “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” <i>Id.</i> at 2:28-2:39. • <i>Id.</i> at 2:28 (showing lysate in the s-channel).

Claim	Claim Language	Infringement Evidence
		 <p>On information and belief, in the accused system extracting the nucleic acids comprises removably receiving a housing comprising a plurality of process chambers in the bay, the plurality of process chambers maintained at a same height relative to one another as the housing is received in and removed from the bay, the plurality of process chambers aligned along a first axis when the housing is received in the bay.</p> <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the

Claim	Claim Language	Infringement Evidence
		<p>set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 10. The method of claim 3, wherein washing the set of moiety-bound nucleic acid particles comprises aspirating the moiety-sample mixture; receiving the cartridge at the cartridge receiving module comprising the set of pins and a cam card interfacing with the set of pins; transitioning the cartridge to an active configuration that disposes the cartridge proximal the set of pins; displacing the first subset of the set of pins in the active configuration of the cartridge, upon translation of the cam card relative to the set of pins, thereby occluding the fluidic pathway of the cartridge at a set of occlusion positions; delivering the moiety-sample mixture into the fluidic pathway, wherein the fluidic pathway is configured to pass through a magnetic field and is coupled to a waste chamber, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field; and delivering a wash solution through the fluidic pathway and into the waste chamber in a continuous flow operation. • Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the

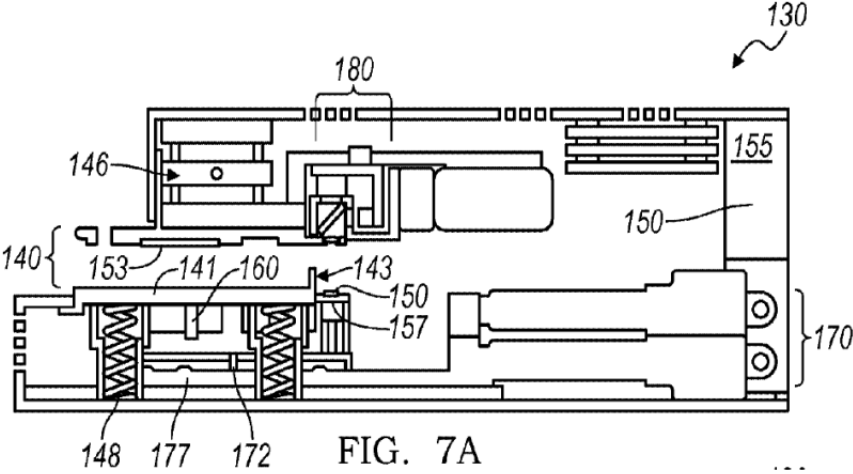
Claim	Claim Language	Infringement Evidence
		<p>cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second subset of the set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction.</p> <ul style="list-style-type: none"> Claim 19. A method for nucleic acid isolation from a biological sample, comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution includes a set of affinity moiety-coated microparticles, comprising a set of microparticles amide-bonded to at least one of Poly(allylamine) of molecular weight <30,000 Da and Polypropylenimine tetramine dendrimer Generation 1; producing a moiety-sample mixture upon combination of the binding moiety solution with the biological sample; producing a set of moiety-bound nucleic acid particles upon incubation of the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of the set of pins includes reversing displacement of at least one pin of the first subset of the set of pins, and reversing occlusion of a portion of the fluidic pathway. Patent No. 9,382,532 at 23:23-28 (“In a specific example, the valve actuation subsystem 170 comprises 12 sets of pins 172 configured to selectively occlude 12 fluidic pathways 212 of a microfluidic cartridge 210 aligned within the molecular diagnostic module; however, other embodiments may comprise any appropriate number of sets of pins 172.”) <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled



Claim	Claim Language	Infringement Evidence
		<p>to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position of the fluidic pathway, by way of the void of the corrugated surface, the fluidic pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber.</p> <ul style="list-style-type: none"> • Claim 4. The cartridge of claim 3, wherein the fluidic pathway comprises a capture segment, downstream of the sample port and configured to cross the magnet housing region multiple times. • U.S. Patent No. 9,403,165 at 1A. <div data-bbox="682 670 1589 1356" data-label="Image"> </div> <p style="text-align: center;">FIG. 1A</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,403,165 at FIG. 1C .


Claim	Claim Language	Infringement Evidence
		<div data-bbox="680 250 1579 565" data-label="Diagram"> <p style="text-align: center;">FIG. 1C</p> </div> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at 7:66-8:22 (“The top layer 110 of the microfluidic cartridge 100 may further comprise a set of cartridge-aligning indentations 180, which function to align the microfluidic cartridge 100 as it moves through an external module... Alternatively, the cartridge-aligning indentations may be grooves, such that the microfluidic cartridge 100 accurately slides into position along the grooves within a system external to the microfluidic cartridge 100. In yet another alternative embodiment, the set of cartridge-aligning indentations 180 may be any appropriate indentations that allow for positioning of the microfluidic cartridge 100 within an external system. However, the microfluidic cartridge 100 may altogether omit the set of cartridge-aligning indentations 180, and rely upon other features of the microfluidic cartridge 100 to facilitate alignment.”) U.S. Patent No. 9,403,165 at 10:35-42 (“In an embodiment of the waste chamber 130 with a corrugated surface 137, at least two ridges of the corrugated surface 137 are preferably the same height, such that the microfluidic cartridge 100 sits substantially level on a flat base. In an alternative embodiment, all ridges of the corrugated surface 137 of the waste chamber 130 are identical, for structural symmetry, and in yet another embodiment, the waste chamber 130 may not have a corrugated surface 137.”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises:

Claim	Claim Language	Infringement Evidence
		<p>a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic

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		<p>beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 2:49-58 (“As shown in FIGS. 1A-1B and 7A, an embodiment of a system 100 for processing and detecting nucleic acids comprises: a capture plate 110 configured to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119; a molecular diagnostic module 130 comprising a microfluidic cartridge receiving module 140, heating and cooling subsystem 150, a magnet 160, a valve actuation subsystem 170, an optical subsystem 180; and an assay strip 190 configured to facilitate mixing of molecular diagnostic reagents with a nucleic acid volume.”) • U.S. Patent No. 9,050,594 at 3:20-28 (“The liquid handling system 250 then aspirates substantially all of each sample of the set of lysed biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate no [sic], and dispenses the set of magnetic bead-samples into a microfluidic cartridge 210, aligned within a cartridge receiving module 140 of a molecular diagnostic module 130, and configured to be manipulated by the molecular diagnostic module 130.”) • U.S. Patent No. 9,050,594 at 7A.

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		 <p>FIG. 7A</p>
1(f)	the bay comprising one or more complementary registration members that receive the housing in a single orientation when the housing is received in the bay	<p>In the accused workflow extracting the nucleic acids comprises removably receiving a housing comprising a plurality of process chambers in the bay, the plurality of process chambers maintained at a same height relative to one another as the housing is received in and removed from the bay, the plurality of process chambers aligned along a first axis when the housing is received in the bay, the bay comprising one or more complementary registration members that receive the housing in a single orientation when the housing is received in the bay.</p> <p><i>NeuMoDx Molecular N288 System</i>, http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ TECHNOLOGY” hyperlink at https://player.vimeo.com/video/281470603. (Exhibit 17)</p> <ul style="list-style-type: none"> At 4:17 (showing a plurality of multi-lane microfluidic cartridges in a plurality of receiving bays)

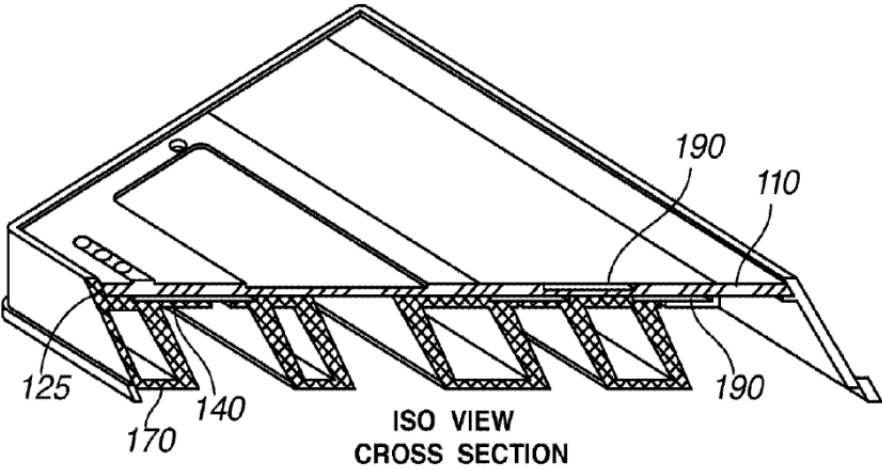
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		 <ul style="list-style-type: none">• at 4:55-5:00 (showing a plurality of multi-lane microfluidic cartridges in a plurality of receiving bays) 

Claim	Claim Language	Infringement Evidence
		<div data-bbox="569 264 1633 561">  </div> <p data-bbox="569 602 1913 816">On information and belief, in the accused system extracting the nucleic acids comprises removably receiving a housing comprising a plurality of process chambers in the bay, the plurality of process chambers maintained at a same height relative to one another as the housing is received in and removed from the bay, the plurality of process chambers aligned along a first axis when the housing is received in the bay, the bay comprising one or more complementary registration members that receive the housing in a single orientation when the housing is received in the bay.</p> <p data-bbox="569 857 884 889">US9382532 (Exhibit 52)</p> <ul data-bbox="615 898 1913 1403" style="list-style-type: none"> • Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein

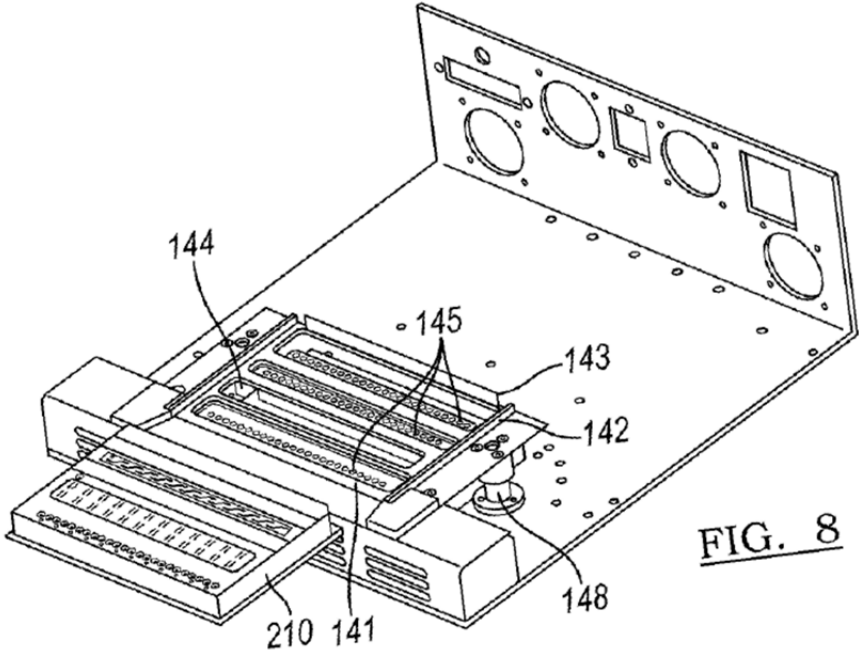
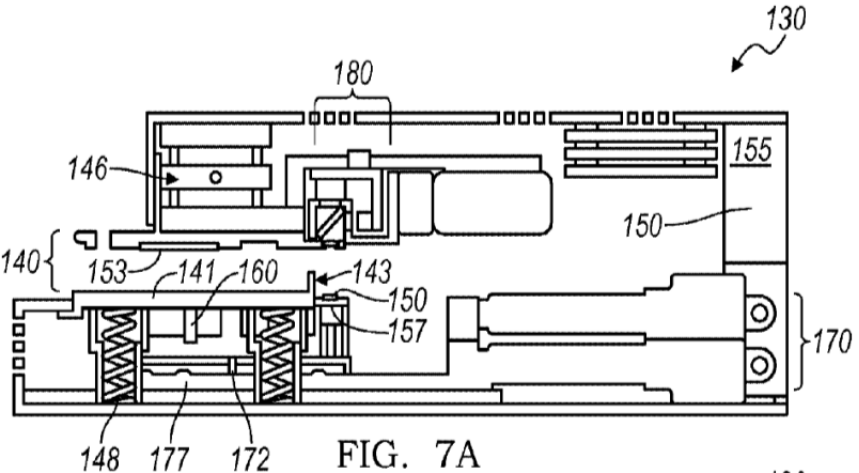
Claim	Claim Language	Infringement Evidence
		<p>displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Clam 10. The method of claim 3, wherein washing the set of moiety-bound nucleic acid particles comprises aspirating the moiety-sample mixture; receiving the cartridge at the cartridge receiving module comprising the set of pins and a cam card interfacing with the set of pins; transitioning the cartridge to an active configuration that disposes the cartridge proximal the set of pins; displacing the first subset of the set of pins in the active configuration of the cartridge, upon translation of the cam card relative to the set of pins, thereby occluding the fluidic pathway of the cartridge at a set of occlusion positions; delivering the moiety-sample mixture into the fluidic pathway, wherein the fluidic pathway is configured to pass through a magnetic field and is coupled to a waste chamber, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field; and delivering a wash solution through the fluidic pathway and into the waste chamber in a continuous flow operation. • Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second subset of the set of pins to

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		<p>modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction.</p> <ul style="list-style-type: none"> Claim 19. A method for nucleic acid isolation from a biological sample, comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution includes a set of affinity moiety-coated microparticles, comprising a set of microparticles amide-bonded to at least one of Poly(allylamine) of molecular weight <30,000 Da and Polypropylenimine tetramine dendrimer Generation 1; producing a moiety-sample mixture upon combination of the binding moiety solution with the biological sample; producing a set of moiety-bound nucleic acid particles upon incubation of the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of the set of pins includes reversing displacement of at least one pin of the first subset of the set of pins, and reversing occlusion of a portion of the fluidic pathway. Patent No. 9,382,532 at 23:23-28 (“In a specific example, the valve actuation subsystem 170 comprises 12 sets of pins 172 configured to selectively occlude 12 fluidic pathways 212 of a microfluidic cartridge 210 aligned within the molecular diagnostic module; however, other embodiments may comprise any appropriate number of sets of pins 172.”) <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position

Claim	Claim Language	Infringement Evidence
		<p>of the fluidic pathway, by way of the void of the corrugated surface, the fluidic pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,403,165 at 7:66-8:22. (“The top layer 110 of the microfluidic cartridge 100 may further comprise a set of cartridge-aligning indentations 180, which function to align the microfluidic cartridge 100 as it moves through an external module... Alternatively, the cartridge-aligning indentations may be grooves, such that the microfluidic cartridge 100 accurately slides into position along the grooves within a system external to the microfluidic cartridge 100. In yet another alternative embodiment, the set of cartridge-aligning indentations 180 may be any appropriate indentations that allow for positioning of the microfluidic cartridge 100 within an external system. However, the microfluidic cartridge 100 may altogether omit the set of cartridge-aligning indentations 180, and rely upon other features of the microfluidic cartridge 100 to facilitate alignment.”) • U.S. Patent No. 9,403,165 at 10:35-42 (“In an embodiment of the waste chamber 130 with a corrugated surface 137, at least two ridges of the corrugated surface 137 are preferably the same height, such that the microfluidic cartridge 100 sits substantially level on a flat base. In an alternative embodiment, all ridges of the corrugated surface 137 of the waste chamber 130 are identical, for structural symmetry, and in yet another embodiment, the waste chamber 130 may not have a corrugated surface 137.”) • U.S. Patent No. 9,403,165 at FIG. 4.

Claim	Claim Language	Infringement Evidence
		 <p data-bbox="997 641 1207 706" style="text-align: center;">ISO VIEW CROSS SECTION</p> <p data-bbox="1039 730 1165 771" style="text-align: center;">FIG. 4</p> <p data-bbox="567 776 882 812">US9050594 (Exhibit 24)</p> <ul data-bbox="619 820 1911 1396" style="list-style-type: none"> • Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-

Claim	Claim Language	Infringement Evidence
		<p>reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 7:53-63 (“As shown in FIG. 9A, the cartridge receiving module 140 of the molecular diagnostic module 130 comprises a cartridge platform 141 including a cartridge loading guiderail 142, a cartridge stop 143, a magnet receiving slot 144, and a set of valve actuation slots 145; a linear actuator 146 configured to displace a microfluidic cartridge 210 resting on the cartridge platform 141, and a set of springs 148 coupled to the cartridge platform 141. The cartridge receiving module 140 thus functions to receive, align, and compress a microfluidic cartridge 210 for processing of a biological sample according to a molecular diagnostic assay protocol.”) • U.S. Patent No. 9,050,594 at 8:7-12 (“The cartridge platform 141 includes a cartridge loading guiderail 142, a cartridge stop 143, a magnet receiving slot 144, and a set of valve actuation slots 145, and functions to receive and align a microfluidic cartridge 210, while providing access to the microfluidic cartridge 210 by a magnet 160 and a valve actuation subsystem 170.”) • U.S. Patent No. 9,050,594 at FIG. 8.

Claim	Claim Language	Infringement Evidence
		 <p>FIG. 8</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 7A.  <p>FIG. 7A</p>

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 22:61-23:20 (“The microfluidic cartridge 210 is preferably configured to be received and manipulated by the molecular diagnostic module 130, such that the cartridge receiving module 140 of the molecular diagnostic module 130 receives and aligns the microfluidic cartridge 210 within the molecular diagnostic module 130, the heating and cooling subsystem 150 of the molecular diagnostic module 130 is configured to transfer heat to the heating region 224 of the microfluidic cartridge 210, and the magnet 160 of the molecular diagnostic module 130 is configured to be received by the magnet housing region 218 of the microfluidic cartridge 210 to provide a magnetic field for separation of nucleic acids... The optical subsystem 180 of the molecular diagnostic module 130 is further configured to align with the set of detection chambers 213 of the microfluidic cartridge 210, to facilitate analysis of a set of nucleic acid samples.”)
1(g)	the magnetic separator of the first module positioned to apply a magnetic force to a first side of the plurality of process chambers when the housing is received in the bay	<p>In the accused workflow extracting the nucleic acids comprises removably receiving a housing comprising a plurality of process chambers in the bay, the plurality of process chambers maintained at a same height relative to one another as the housing is received in and removed from the bay, the plurality of process chambers aligned along a first axis when the housing is received in the bay, the bay comprising one or more complementary registration members that receive the housing in a single orientation when the housing is received in the bay, the magnetic separator of the first module positioned to apply a magnetic force to a first side of the plurality of process chambers when the housing is received in the bay.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” <i>Id.</i> at 2:28-2:39. <i>Id.</i> at 2:28 (showing lysate in the s-channel).

Claim	Claim Language	Infringement Evidence
		 <p data-bbox="569 808 884 846">US9382532 (Exhibit 52)</p> <ul data-bbox="615 850 1921 1395" style="list-style-type: none"> • Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of

Claim	Claim Language	Infringement Evidence
		<p>the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 5. The method of claim 3, wherein separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture. • Claim 6. The method of claim 5, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety-sample mixture from the process chamber; occluding the fluidic pathway of the cartridge-at a set of occlusion positions upon displacement of pins of the set of pins to generate a path through a magnetic field, and to a waste chamber; and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber. • Claim 10. The method of claim 3, wherein washing the set of moiety-bound nucleic acid particles comprises aspirating the moiety-sample mixture; receiving the cartridge at the cartridge receiving module comprising the set of pins and a cam card interfacing with the set of pins; transitioning the cartridge to an active configuration that disposes the cartridge proximal the set of pins; displacing the first subset of the set of pins in the active configuration of the cartridge, upon translation of the cam card relative to the set of pins, thereby occluding the fluidic pathway of the cartridge at a set of occlusion positions; delivering the moiety-sample mixture into the fluidic pathway, wherein the fluidic pathway is configured to pass through a magnetic field and is coupled to a waste chamber, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field; and delivering a wash solution through the fluidic pathway and into the waste chamber in a continuous flow operation.. • Claim 14. The method of claim 13, further comprising capturing the set of moiety-bound nucleic acid particles within the magnetic field and aspirating the nucleic acid sample from the fluidic pathway. • Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity

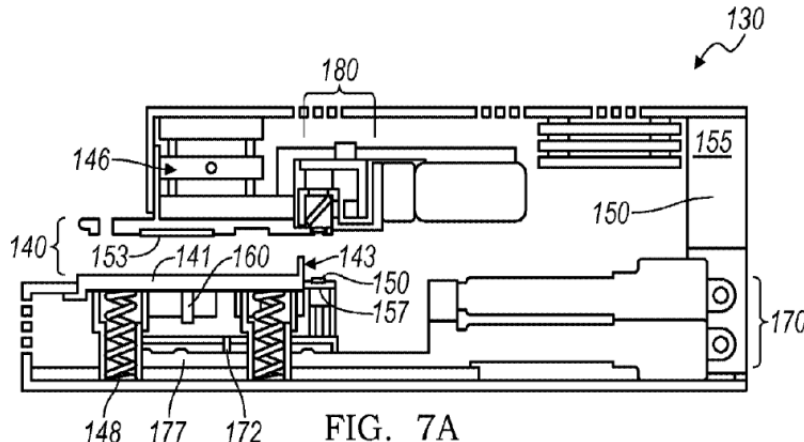
Claim	Claim Language	Infringement Evidence
		<p>moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second subset of the set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction.</p> <ul style="list-style-type: none"> • Claim 18. The method of claim 17, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety-sample mixture from the process chamber; occluding the fluidic pathway of the cartridge at a set of occlusion positions upon displacement of the first subset of the set of pins to generate a path through a magnetic field, and to a waste chamber of the cartridge; and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber. • U.S. Patent No. 9,382,532 at 7:31-39 (“In a second variation, the lysed moiety-sample solution can be transferred to a vessel that enables the moiety-bound nucleic acid volume to be captured and the waste volume to be removed in a flow through manner, either against the pores of a filter or in the presence of a magnetic field. In the second variation, the microparticles with bound nucleic acids are retained in a filter zone or a magnetic field zone of the vessel, and the liquid portion is flowed into a "waste chamber".”) • Patent No. 9,382,532 at 8:48-55 (“In the variation of the first example, the microparticles of the moiety-bound nucleic acid volume can be retained by a magnetic field within a portion of the fluidic pathway upon occlusion of the fluidic pathway at a suitable set of occlusion positions,

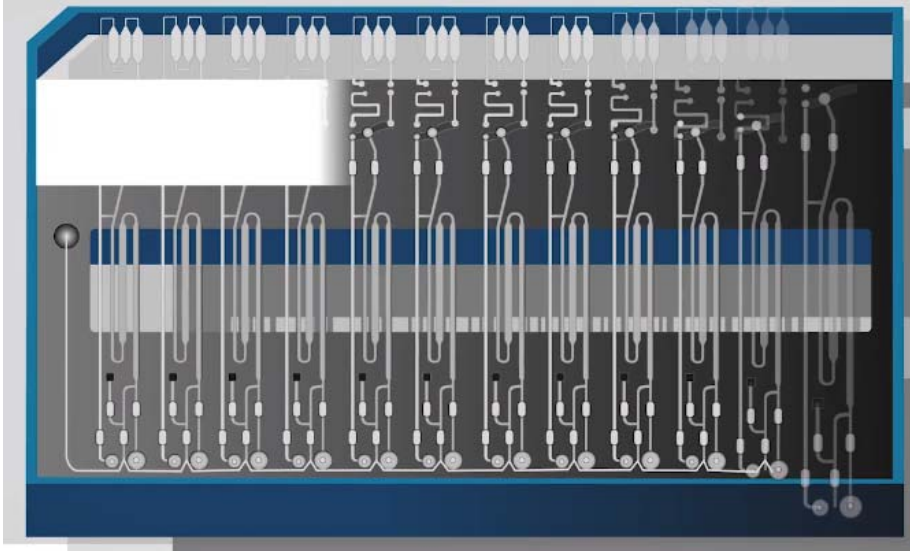
Claim	Claim Language	Infringement Evidence
		<p>and the wash solution can be delivered through the portion of the fluidic pathway and into a waste chamber of the cartridge to wash the microparticles with the bound target nucleic acid(s).”)</p> <ul style="list-style-type: none"> • Patent No. 9,382,532 at 11:6-14 (“In a specific example of this variation, a system (such as the one described in U.S. patent application Ser. No. 13/766,359, entitled "System and Method for Processing and Detecting Nucleic Acids") can be used to aspirate the nucleic acid sample from a fluidic path way of a cartridge (such as the one described in U.S. patent application Ser. No. 13/765,996, entitled "Microfluidic Cartridge for Processing and Detecting Nucleic Acids"), while the microparticles are immobilized by a magnet.”) • Patent No. 9,382,532 at 24:65-25:2 (“Nucleic acids bound to magnetic beads may thus be trapped within the capture segment 166 by the magnetic field 156, while other substances in the volume of sample fluid may pass into the waste chamber 130 by passing the fifth occlusion position 146.”) <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> • Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position of the fluidic pathway, by way of the void of the corrugated surface, the fluidic pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber. • Claim 3. The cartridge of claim 1, wherein the waste chamber comprises at least one waste inlet in communication with the opening of the intermediate substrate, and wherein the corrugated surface of the waste chamber further defines a rectangular prismatic void spanning a long dimension of the cartridge that defines a magnet housing region configured to reversibly receive a magnet from the direction perpendicular to a broad face of the first layer, and configured to cross the fluidic pathway. • Claim 4. The cartridge of claim 3, wherein the fluidic pathway comprises a capture segment,

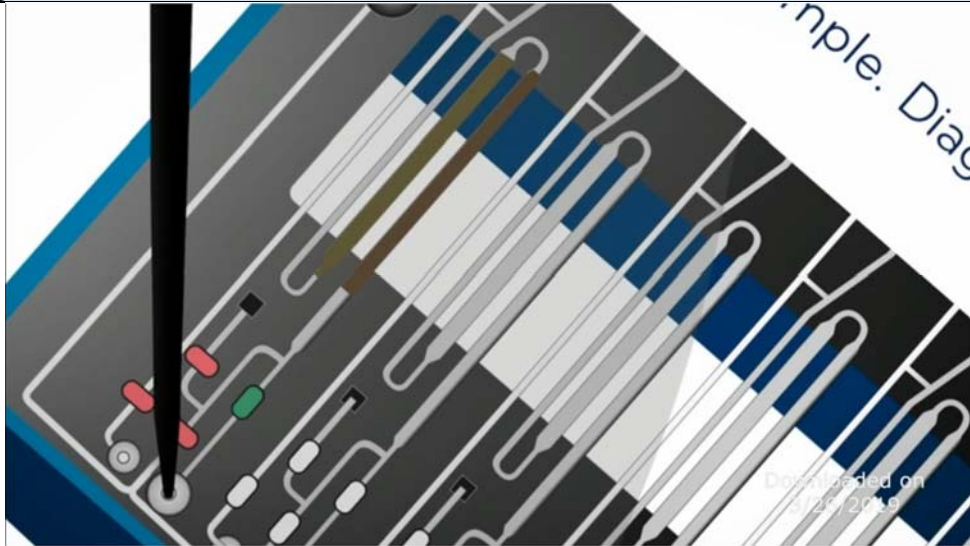
Claim	Claim Language	Infringement Evidence
		<p>downstream of the sample port and configured to cross the magnet housing region multiple times.</p> <ul style="list-style-type: none"> • Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate. • Claim 15. The cartridge of claim 8, wherein at least one void of the set of voids defined by the corrugated surface of the waste chamber is a rectangular prismatic void spanning a long dimension of the cartridge and defining a magnet housing region configured to cross the first fluidic pathway and the second fluidic pathway. • U.S. Patent No. 9,403,165 at 2:39-63 (“As shown in FIGS. 1A-1C, an embodiment of a microfluidic cartridge 100 for processing and detecting nucleic acids comprises: a top layer 110 comprising a set of sample port-reagent port pairs 112 and a set of detection chambers 116; an intermediate substrate 120, coupled to the top layer 110 and partially separated from the top layer by a film layer 125, configured to form a waste chamber 130; an elastomeric layer 140 partially situated on the intermediate substrate 120; a magnet housing region 150 accessible by a magnet 152 providing a magnetic field 156; and a set of fluidic pathways 160, each formed by at least a portion of the top layer 110, a portion of the film layer 125, and a portion of the elastomeric layer 140. In other embodiments, the microfluidic cartridge 100 may further comprise a bottom layer 170 coupled to the intermediate substrate 120 and configured to seal the waste chamber 130. Furthermore, the top layer 110 of the microfluidic cartridge 100 may further comprise a shared fluid port 118, a vent region 190, and a heating region 195, such that each fluidic pathway 165 in the set of fluidic pathways 160 is fluidically coupled to a sample port-reagent port pair 113, the shared fluid port 118, the waste chamber 130, and a detection chamber 117, comprises a capture segment 166 configured to pass through the heating region and the magnetic field, and is configured to pass through the vent region 190 upstream of the detection chamber 117.”)

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at 12:38-41 (“The magnet housing region 150 of the microfluidic cartridge 100 functions to provide access to and/or house at least one magnet 152 providing a magnetic field 156 for purification and isolation of nucleic acids.”) U.S. Patent No. 9,403,165 at 21:17-21 (“Multiple fluidic pathways may be configured to pass through a single heating region 195 of the microfluidic cartridge 100, a single vent region 190 of the microfluidic cartridge 100, and/or a magnetic field 156 produced by a magnet 152 housed within a single magnet housing region 150.”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. Claim 8. The system of claim 1, wherein the magnet is configured to provide a magnetic field spanning at least three fluidic pathways configured to facilitate isolation and extraction of three nucleic acid volumes. Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate

Claim	Claim Language	Infringement Evidence
		<p>comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 23. A system for processing and detecting nucleic acids, comprising: a molecular diagnostic module, configured to process a set of biological samples combined with magnetic beads and separate a set of nucleic acid volumes from the set of biological samples combined with magnetic beads, wherein the molecular diagnostic module comprises an actuator configured to displace a cartridge, a set of pins, and at least one cam contacting the set of pins, wherein an extension or retraction of the actuator moves the cartridge, and a displacement of a subset of the set of pins defines a set of pathways in the cartridge, each configured to receive a biological sample combined with magnetic beads of the set of biological samples combined with magnetic beads. • U.S. Patent No. 9,050,594 at 8:2-8:6 (“The magnet receiving slot 144 and the set of valve actuation slots 145 provide access, by a magnet 160 and a valve actuation subsystem 170, to the microfluidic cartridge 210, as the microfluidic cartridge is vertically displaced by the linear actuator 146.”) • U.S. Patent No. 9,050,594 at FIG. 7A

Claim	Claim Language	Infringement Evidence
		 <p style="text-align: center;">FIG. 7A</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 12:64-13:1 (“The magnet 160 of the molecular diagnostic module 130 functions to provide a magnetic field for isolation and extraction of nucleic acids bound to magnetic beads within a microfluidic cartridge 210, aligned within the molecular diagnostic module 130.”)
1(h)	the magnetic separator comprising one or more magnets aligned along a second axis parallel to the first axis when the housing is received in the bay	<p>In the accused workflow extracting the nucleic acids comprises removably receiving a housing comprising a plurality of process chambers in the bay, the plurality of process chambers maintained at a same height relative to one another as the housing is received in and removed from the bay, the plurality of process chambers aligned along a first axis when the housing is received in the bay, the bay comprising one or more complementary registration members that receive the housing in a single orientation when the housing is received in the bay, the magnetic separator of the first module positioned to apply a magnetic force to a first side of the plurality of process chambers when the housing is received in the bay, the magnetic separator comprising one or more magnets aligned along a second axis parallel to the first axis when the housing is received in the bay.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12

Claim	Claim Language	Infringement Evidence
		<p data-bbox="661 235 1869 300">independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1: :59</p>  <ul data-bbox="619 860 1921 998" style="list-style-type: none"> • “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” <i>Id.</i> at 2:28-2:39. • <i>Id.</i> at 2:28 (showing lysate in the s-channel).

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		 <p>On information and belief, in the accused workflow extracting the nucleic acids comprises removably receiving a housing comprising a plurality of process chambers in the bay, the plurality of process chambers maintained at a same height relative to one another as the housing is received in and removed from the bay, the plurality of process chambers aligned along a first axis when the housing is received in the bay, the bay comprising one or more complementary registration members that receive the housing in a single orientation when the housing is received in the bay, the magnetic separator of the first module positioned to apply a magnetic force to a first side of the plurality of process chambers when the housing is received in the bay, the magnetic separator comprising one or more magnets aligned along a second axis parallel to the first axis when the housing is received in the bay.</p> <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the

Claim	Claim Language	Infringement Evidence
		<p>process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 10. The method of claim 3, wherein washing the set of moiety-bound nucleic acid particles comprises aspirating the moiety-sample mixture; receiving the cartridge at the cartridge receiving module comprising the set of pins and a cam card interfacing with the set of pins; transitioning the cartridge to an active configuration that disposes the cartridge proximal the set of pins; displacing the first subset of the set of pins in the active configuration of the cartridge, upon translation of the cam card relative to the set of pins, thereby occluding the fluidic pathway of the cartridge at a set of occlusion positions; delivering the moiety-sample mixture into the fluidic pathway, wherein the fluidic pathway is configured to pass through a magnetic field and is coupled to a waste chamber, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field; and delivering a wash solution through the fluidic pathway and into the waste chamber in a continuous flow operation.. • Claim 13. The method of claim 3, wherein releasing the nucleic acid sample from the set of moiety-bound nucleic acid particles comprises occluding the fluidic pathway of the cartridge, comprising the process chamber, at a set of occlusion positions, upon displacement of pins of the set of pins, to define a path through a magnetic field; delivering the set of moiety-bound nucleic acid particles into the path of the fluidic pathway; and delivering an elution solution into the fluidic pathway, thereby inducing a pH shift configured to release the nucleic acid sample from the set of moiety-bound nucleic acid particles. • Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and

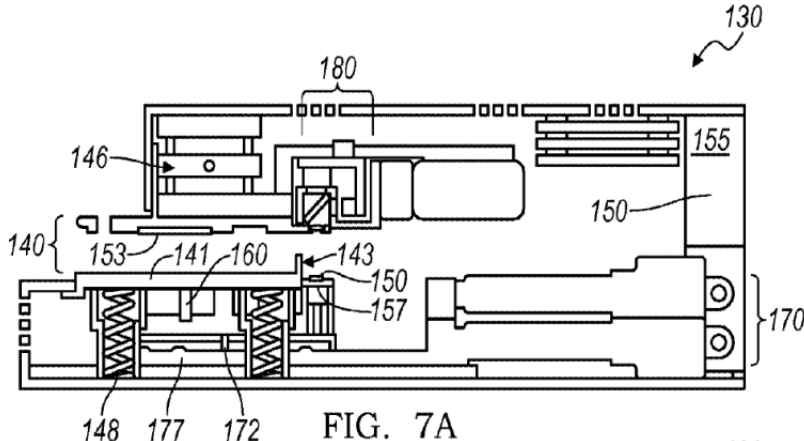
Claim	Claim Language	Infringement Evidence
		<p>concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second subset of the set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction.</p> <ul style="list-style-type: none"> • Claim 18. The method of claim 17, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety-sample mixture from the process chamber; occluding the fluidic pathway of the cartridge at a set of occlusion positions upon displacement of the first subset of the set of pins to generate a path through a magnetic field, and to a waste chamber of the cartridge; and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber. • Patent No. 9,382,532 at 8:48-55 (“In the variation of the first example, the microparticles of the moiety-bound nucleic acid volume can be retained by a magnetic field within a portion of the fluidic pathway upon occlusion of the fluidic pathway at a suitable set of occlusion positions, and the wash solution can be delivered through the portion of the fluidic pathway and into a waste chamber of the cartridge to wash the microparticles with the bound target nucleic acid(s).”) • Patent No. 9,382,532 at 10:3-13 (“In the variation of the specific example, the microparticles of the moiety-bound nucleic acid volume can be retained by a magnetic field within a portion

Claim	Claim Language	Infringement Evidence
		<p>of the fluidic pathway upon occlusion of the fluidic pathway at a suitable set of occlusion positions, and the elution solution can be delivered through the portion of the fluidic pathway enable release of the nucleic acid sample from the microparticle. Additionally, a heating element of the system can be moved proximal to the portion of the fluidic pathway with the elution solution and the microparticles to further enhance release of the nucleic acid sample.”)</p> <ul style="list-style-type: none"> • Patent No. 9,382,532 at 11:6-14 (“In a specific example of this variation, a system (such as the one described in U.S. patent application Ser. No. 13/766,359, entitled "System and Method for Processing and Detecting Nucleic Acids") can be used to aspirate the nucleic acid sample from a fluidic path way of a cartridge (such as the one described in U.S. patent application Ser. No. 13/765,996, entitled "Microfluidic Cartridge for Processing and Detecting Nucleic Acids"), while the microparticles are immobilized by a magnet..”) <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> • Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position of the fluidic pathway, by way of the void of the corrugated surface, the fluidic pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber. • Claim 3. The cartridge of claim 1, wherein the waste chamber comprises at least one waste inlet in communication with the opening of the intermediate substrate, and wherein the corrugated surface of the waste chamber further defines a rectangular prismatic void spanning a long dimension of the cartridge that defines a magnet housing region configured to reversibly receive a magnet from the direction perpendicular to a broad face of the first layer, and configured to cross the fluidic pathway. • Claim 4. The cartridge of claim 3, wherein the fluidic pathway comprises a capture segment, downstream of the sample port and configured to cross the magnet housing region multiple


Claim	Claim Language	Infringement Evidence
		<p>times.</p> <ul style="list-style-type: none"> • Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate. • Claim 15. The cartridge of claim 8, wherein at least one void of the set of voids defined by the corrugated surface of the waste chamber is a rectangular prismatic void spanning a long dimension of the cartridge and defining a magnet housing region configured to cross the first fluidic pathway and the second fluidic pathway. • U.S. Patent No. 9,403,165 at 2:39-63 (“As shown in FIGS. 1A-1C, an embodiment of a microfluidic cartridge 100 for processing and detecting nucleic acids comprises: a top layer 110 comprising a set of sample port-reagent port pairs 112 and a set of detection chambers 116; an intermediate substrate 120, coupled to the top layer 110 and partially separated from the top layer by a film layer 125, configured to form a waste chamber 130; an elastomeric layer 140 partially situated on the intermediate substrate 120; a magnet housing region 150 accessible by a magnet 152 providing a magnetic field 156; and a set of fluidic pathways 160, each formed by at least a portion of the top layer 110, a portion of the film layer 125, and a portion of the elastomeric layer 140. In other embodiments, the microfluidic cartridge 100 may further comprise a bottom layer 170 coupled to the intermediate substrate 120 and configured to seal the waste chamber 130. Furthermore, the top layer 110 of the microfluidic cartridge 100 may further comprise a shared fluid port 118, a vent region 190, and a heating region 195, such that each fluidic pathway 165 in the set of fluidic pathways 160 is fluidically coupled to a sample port-reagent port pair 113, the shared fluid port 118, the waste chamber 130, and a detection chamber 117, comprises a capture segment 166 configured to pass through the heating region and the magnetic field, and is configured to pass through the vent region 190 upstream of the detection chamber 117.”) • U.S. Patent No. 9,403,165 at 12:59-13:2 (“Preferably, the magnet housing region 150 is bounded


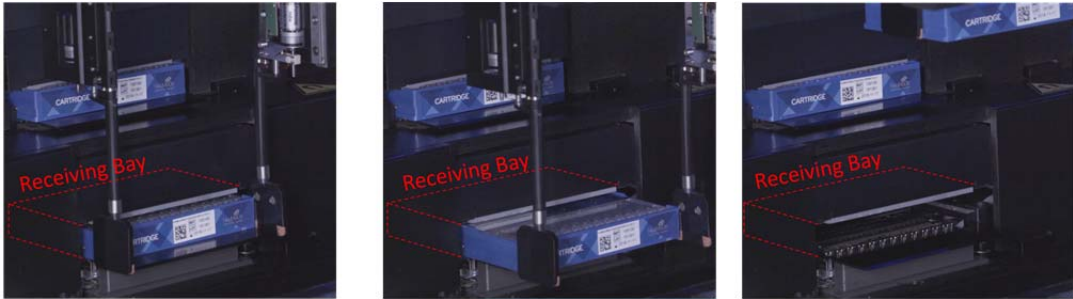
Claim	Claim Language	Infringement Evidence
		<p>on at least two sides by the waste chamber 130, and positioned near the middle of the microfluidic cartridge 100, such that a fluidic pathway 165 passing through the magnetic field 156 passes through the magnetic field 156 at least at one point along an intermediate portion of the fluidic pathway 165. Preferably, the magnet housing region 150 also substantially spans at least one dimension of the microfluidic cartridge, such that multiple fluidic pathways 165 of the microfluidic cartridge 100 cross the same magnet housing region 150, magnet 152, and/or magnetic field 156.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,403,165 at 21:17-32 (“Multiple fluidic pathways may be configured to pass through a single heating region 195 of the microfluidic cartridge 100, a single vent region 190 of the microfluidic cartridge 100, and/or a magnetic field 156 produced by a magnet 152 housed within a single magnet housing region 150. Preferably all fluidic pathways of the set of fluidic pathways 160 are configured to pass through a single heating region 195 of the microfluidic cartridge 100, a single vent region 190 of the microfluidic cartridge 100, and a magnetic field 156 produced by a magnet 152 housed within a single magnet housing region 150; however, alternative embodiments of the set of fluidic pathways 160 of the microfluidic cartridge may comprise different configurations wherein fluidic pathways of the set of fluidic pathways 160 do not share a single heating region 195, a single vent region 190, and/or a magnetic field 156.”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 7. The system of claim 1, wherein a retracted configuration of the actuator allows the

Claim	Claim Language	Infringement Evidence
		<p>magnet to retract from the magnet receiving slot.</p> <ul style="list-style-type: none"> • Claim 8. The system of claim 1, wherein the magnet is configured to provide a magnetic field spanning at least three fluidic pathways configured to facilitate isolation and extraction of three nucleic acid volumes. • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • U.S. Patent No. 9,050,594 at 2:49-58 (“As shown in FIGS. 1A-1B and 7A, an embodiment of a system 100 for processing and detecting nucleic acids comprises: a capture plate 110 configured to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119; a molecular diagnostic module 130 comprising a microfluidic cartridge receiving module 140, heating and cooling subsystem 150, a magnet 160, a valve actuation subsystem 170, an optical subsystem 180; and an assay strip 190 configured to facilitate mixing of molecular diagnostic reagents with a nucleic acid volume.”) • U.S. Patent No. 9,050,594 at 7:63-8:6 (“As shown in FIGS. 7A-7C, the cartridge platform 141 is preferably configured to receive a microfluidic cartridge 210 along a cartridge loading guiderail 142 until it reaches a cartridge stop 143, and be vertically displaced by the linear actuator 146, which places a biasing force against the set of springs 148 coupled to the cartridge platform 141. The magnet receiving slot 144 and the set of valve actuation slots 145 provide access, by a magnet 160 and a valve actuation subsystem 170, to the microfluidic cartridge 210, as the microfluidic cartridge is vertically displaced by the linear actuator 146.”) • U.S. Patent No. 9,050,594 at FIG. 7A

Claim	Claim Language	Infringement Evidence
		 <p style="text-align: center;">FIG. 7A</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 8:36-53 (“The embodiment of the cartridge platform 141 shown in FIG. 8 also includes a set of valve actuation slots 145, oriented perpendicular to the parallel cartridge loading guiderails 142 and configured to provide access to a valve actuation subsystem 170, and a magnet receiving slot 144 located among the set of valve actuation slots 145. Preferably, the magnet receiving slot 144 and the set of valve actuation slots 145 substantially span a long dimension of the cartridge platform 141, as shown in FIG. 8, and are configured to correspond to locations on a microfluidic cartridge 210 requiring a magnetic field and/or valving to enable processing of a biological sample and nucleic acid detection once the microfluidic cartridge 210 has been aligned within the molecular diagnostic module 130. Thus, alternative configurations of the magnet receiving slot 144 and the set of valve actuation slots 145 may accommodate other cartridges with alternative regions requiring magnetic fields and/or valving to enable other protocols.”) U.S. Patent No. 9,050,594 at 12:64-13:18 (“The magnet 160 of the molecular diagnostic module 130 functions to provide a magnetic field for isolation and extraction of nucleic acids bound to magnetic beads within a microfluidic cartridge 210, aligned within the molecular diagnostic module 130. Preferably, the magnet 160 is fixed within the molecular diagnostic module 130, such that the extended configuration 146 b of the linear actuator 146 allows the magnet 160 to pass through the magnet receiving slot 144 of the cartridge receiving module 140 and into a magnet housing region 218 of the microfluidic cartridge 210. In an example, as shown

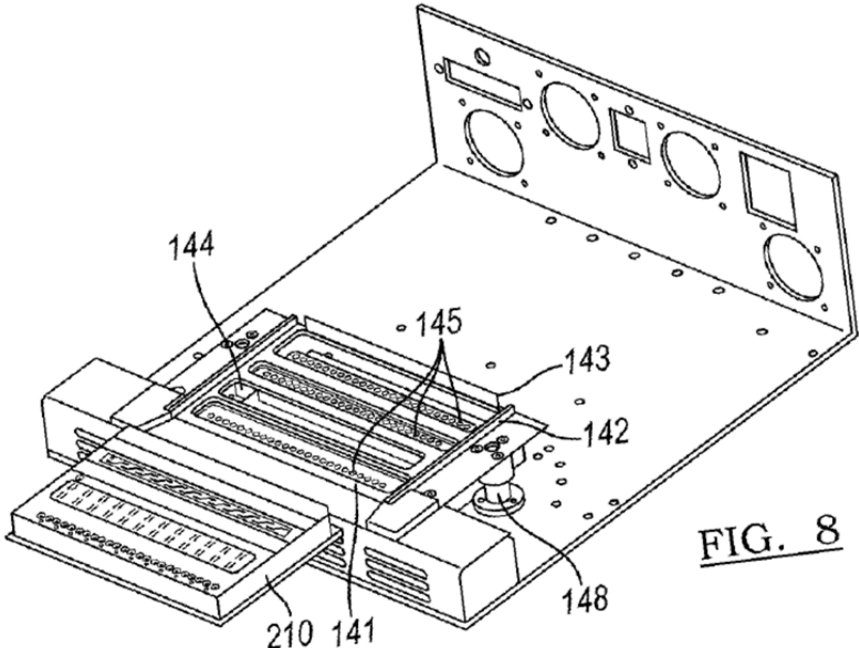
Claim	Claim Language	Infringement Evidence
		<p>in FIGS. 7A-7C, the magnet 160 is a rectangular prism-shaped magnet 160 fixed under the cartridge platform 141, and configured to pass through the cartridge platform 141, into a magnet housing region 218 located under the heating region 224 of the microfluidic cartridge 210. Preferably, the magnet 160 is one of two or three magnets lined up in parallel, such that each of the fluidic pathways of a microfluidic cartridge housing the magnets is exposed to two or three times as much magnetic flux, and two to threes [sic] times as many opportunities to capture magnetic beads. Alternatively, the magnet 160 is a single magnet configured to expose a set of fluidic pathways to a magnetic field.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 13:26-43 (“In one variation, the magnet 160 or group of multiple magnets comprises a permanent magnet, composed of a magnetized material (e.g., a ferromagnet) providing a substantially fixed magnetic field. In an alternative variation, the magnet 160 or group of multiple magnets comprises an electromagnet configured to provide a modifiable magnetic field, such that the intensity of the magnetic field can be adjusted, the polarity of the magnetic field can be reversed, and the magnetic field can be substantially removed upon removal of a current flowing within the electromagnet. Preferably, the magnet 160 or group of magnets is also fixed relative to the molecular diagnostic module 130; however, the magnet 160 or group of magnets may alternatively be configured to translate vertically (in the orientation shown in FIG. 7B), such that the magnet 160 or group of magnets can extend into and retract from the magnet receiving slot 144 of the cartridge platform 141 and the magnet housing region 218 of the microfluidic cartridge 210.”) • U.S. Patent No. 9,050,594 at 12:64-13:1 (“The magnet 160 of the molecular diagnostic module 130 functions to provide a magnetic field for isolation and extraction of nucleic acids bound to magnetic beads within a microfluidic cartridge 210, aligned within the molecular diagnostic module 130.”) • U.S. Patent No. 9,050,594 at 22:61-23:5 (“The microfluidic cartridge 210 is preferably configured to be received and manipulated by the molecular diagnostic module 130, such that the cartridge receiving module 140 of the molecular diagnostic module 130 receives and aligns the microfluidic cartridge 210 within the molecular diagnostic module 130, the heating and cooling subsystem 150 of the molecular diagnostic module 130 is configured to transfer heat to the heating region 224 of the microfluidic cartridge 210, and the magnet 160 of the molecular diagnostic module 130 is configured to be received by the magnet housing region 218 of the microfluidic cartridge 210 to provide a magnetic field for separation of nucleic acids.”)

Claim	Claim Language	Infringement Evidence
1(i)	the one or more complementary registration members aligning the plurality of process chambers with the magnetic separator when the housing is received in the bay	<p>In the accused workflow extracting the nucleic acids comprises removably receiving a housing comprising a plurality of process chambers in the bay, the plurality of process chambers maintained at a same height relative to one another as the housing is received in and removed from the bay, the plurality of process chambers aligned along a first axis when the housing is received in the bay, the bay comprising one or more complementary registration members that receive the housing in a single orientation when the housing is received in the bay, the magnetic separator of the first module positioned to apply a magnetic force to a first side of the plurality of process chambers when the housing is received in the bay, the magnetic separator comprising one or more magnets aligned along a second axis parallel to the first axis when the housing is received in the bay, the one or more complementary registration members aligning the plurality of process chambers with the magnetic separator when the housing is received in the bay.</p> <p><i>NeuMoDx Molecular N288 System</i>, http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ TECHNOLOGY” hyperlink at https://player.vimeo.com/video/281470603. (Exhibit 17)</p> <ul style="list-style-type: none"> At 4:17 (showing a plurality of multi-lane microfluidic cartridges in a plurality of receiving bays) 

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> at 4:55-5:00 (showing a plurality of multi-lane microfluidic cartridges in a plurality of receiving bays)   <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises:

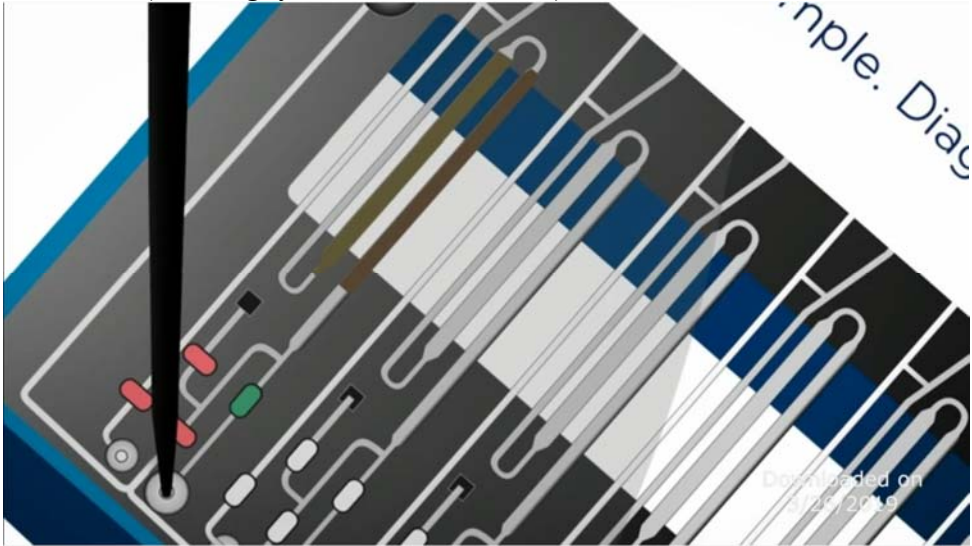
Claim	Claim Language	Infringement Evidence
		<p>a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • U.S. Patent No. 9,050,594 at 7:53-8:6 (“As shown in FIG. 9A, the cartridge receiving module 140 of the molecular diagnostic module 130 comprises a cartridge platform 141 including a cartridge loading guiderail 142, a cartridge stop 143, a magnet receiving slot 144, and a set of valve actuation slots 145; a linear actuator 146 configured to displace a microfluidic cartridge 210 resting on the cartridge platform 141, and a set of springs 148 coupled to the cartridge platform 141. The cartridge receiving module 140 thus functions to receive, align, and compress a microfluidic cartridge 210 for processing of a biological sample according to a molecular diagnostic assay protocol. As shown in FIGS. 7A-7C, the cartridge platform 141 is preferably configured to receive a microfluidic cartridge 210 along a cartridge loading guiderail 142 until it reaches a cartridge stop 143, and be vertically displaced by the linear actuator 146, which places a biasing force against the set of springs 148 coupled to the cartridge platform 141. The magnet receiving slot 144 and the set of valve actuation slots 145 provide access, by a magnet 160 and a valve actuation subsystem 170, to the microfluidic cartridge 210, as the microfluidic cartridge is vertically displaced by the linear actuator 146.”) • U.S. Patent No. 9,050,594 at 7A.

Claim	Claim Language	Infringement Evidence
		<div data-bbox="709 235 1564 706" data-label="Image"> <p>FIG. 7A</p> </div> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 8:7-35 (“The cartridge platform 141 includes a cartridge loading guiderail 142, a cartridge stop 143, a magnet receiving slot 144, and a set of valve actuation slots 145, and functions to receive and align a microfluidic cartridge 210, while providing access to the microfluidic cartridge 210 by a magnet 160 and a valve actuation subsystem 170. As shown in FIG. 8, an embodiment of the cartridge platform 141 includes a pair of parallel cartridge loading guiderails 142, initiating at a pair of inwardly tapering protrusions configured to guide a microfluidic cartridge toward the pair of parallel cartridge loading guiderails 142, and spanning two short edges of the cartridge platform 141. The embodiment of the cartridge platform 141 also includes a cartridge stop 143 comprising a vertical tab oriented perpendicular to the cartridge loading guiderails 142, and spanning a long edge of the cartridge platform. Preferably, the cartridge loading guiderails 142 and the cartridge stop 143 are configured such that a microfluidic cartridge 210 slides between the cartridge loading guiderails 142 and hits the cartridge stop 143 to signal proper alignment. Alternatively, the cartridge loading guiderails 142 and the cartridge stop 143 may be configured such that a microfluidic cartridge slides over or along the cartridge loading guiderails 142, after which the cartridge stop 143 couples to a portion of the microfluidic cartridge 210 to ensure proper alignment of the microfluidic cartridge. Additional variations of the cartridge loading guiderails 142 and the cartridge stop 143 may be used to enable reception and alignment of a microfluidic cartridge 210”).

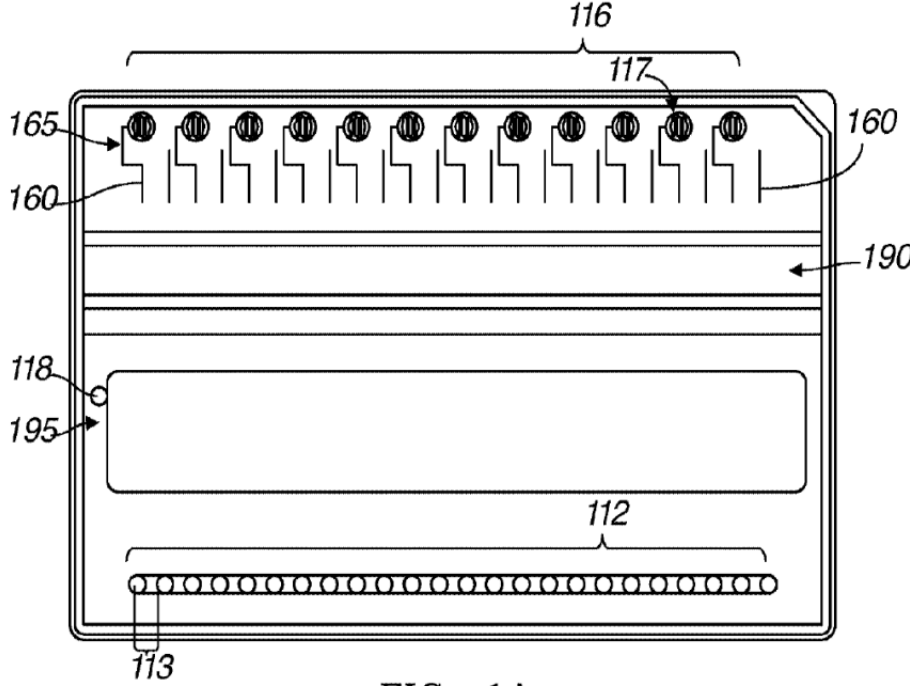
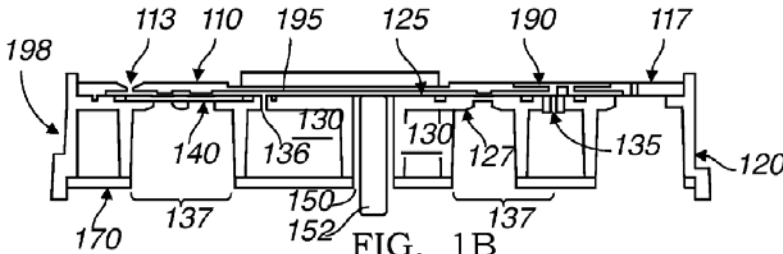
Claim	Claim Language	Infringement Evidence
		<p>by the molecular diagnostic module 130, and are known by those skilled in the art.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at FIG. 8.  <p>FIG. 8</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 8:36-59 (“The embodiment of the cartridge platform 141 shown in FIG. 8 also includes a set of valve actuation slots 145, oriented perpendicular to the parallel cartridge loading guiderails 142 and configured to provide access to a valve actuation subsystem 170, and a magnet receiving slot 144 located among the set of valve actuation slots 145. Preferably, the magnet receiving slot 144 and the set of valve actuation slots 145 substantially span a long dimension of the cartridge platform 141, as shown in FIG. 8, and are configured to correspond to locations on a microfluidic cartridge 210 requiring a magnetic field and/or valving to enable processing of a biological sample and nucleic acid detection once the microfluidic cartridge 210 has been aligned within the molecular diagnostic module 130. Thus, alternative configurations of the magnet receiving slot 144 and the set of valve actuation slots 145 may accommodate other cartridges with alternative regions requiring magnetic fields and/or valving to enable other protocols. In one alternative embodiment, the magnet receiving

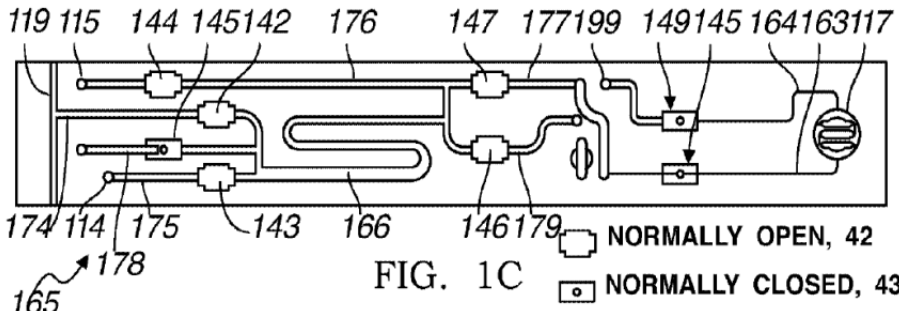
Claim	Claim Language	Infringement Evidence
		<p>slot 144 and the set of valve actuation slots may comprise one continuous void of the cartridge platform 141, such that the cartridge platform 141 supports a microfluidic cartridge 210 along the periphery of the microfluidic cartridge 210, but forms a continuous void under a majority of the footprint of the microfluidic cartridge 210.”)</p> <ul style="list-style-type: none"> <p>U.S. Patent No. 9,050,594 at 8:60-9:32 (“The linear actuator 146 functions to linearly displace a microfluidic cartridge 210 resting on the cartridge platform 141, in order to compress the microfluidic cartridge 210 and position the microfluidic cartridge 210 between a cartridge heater 153 and an optical subsystem 180 on one side of the microfluidic cartridge 210, and a magnet 160 and detection chamber heaters 157 on another side of the microfluidic cartridge 210. The linear actuator 146 also functions to provide a sufficient counterforce to the valve actuation subsystem 170 such that a microfluidic cartridge 210 within the molecular diagnostic module 130 remains properly situation upon manipulation by the valve actuation subsystem 170. The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210. In the orientation of the molecular diagnostic module 130 shown in FIGS. 7B and 7B, the linear actuator 146 is preferably coupled to a portion of the heating and cooling subsystem 150 a portion of the optical subsystem 180, and the nozzle 149, and vertically displaces the cartridge heater 153, the optical subsystem 180, and the nozzle 149 to position the cartridge heater 153, 180 and the nozzle 149 over the microfluidic cartridge 210. The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR). Preferably, the linear actuator 146 is a scissor jack actuator configured to apply substantially uniform pressure over all occlusion positions of a microfluidic cartridge 210 aligned within the molecular diagnostic module 130, and to operate in at least two configurations. In a retracted configuration 146 a, as shown in FIG. 9A, the scissor jack actuator has not linearly displaced the cartridge platform 141, and in an extended configuration 146 b, as shown in FIG. 9B, the scissor jack actuator has linearly displaced the microfluidic cartridge 210 to position the microfluidic cartridge 210 between the subsystems 153, and 180, and the magnet 160 and detection chamber heaters 157.”)</p> <p>U.S. Patent No. 9,050,594 at 10:5-26 (“Similarly, the nozzle 149, the heating and cooling subsystem 150, the cartridge heater 153, and the magnet 160 are preferably coupled to</p>

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		<p>springs, such that springs are positioned between elements 149,150, 153, and 160, and substrates that elements 149, 150, 153, and 160 are mounted to. Alternatively an elastomeric material is preferably positioned between elements 149,150, 153, and 160, and substrates that elements 149, 150, 153, and 160 are mounted to. The springs and/or elastomeric material function to provide proper functioning and alignment of subsystems of the molecular diagnostic module 130 as the linear actuator 146 is extended or retracted, contributing to reliability and a reduction in stack up tolerance risk. The springs and/or elastomeric material further function to allow more pressure to be applied to occlusion positions of a microfluidic cartridge 210 aligned within the molecular diagnostic module 130, and an appropriate pressure to be applied to elements 149, 150, 153 and 160 of the molecular diagnostic module 130. Thus, proper contact is maintained between elements 149, 150, 153, and 160, and a microfluidic cartridge 210 being manipulated by the molecular diagnostic module. These elements are described in further detail below.”)</p>
1(j)	<p>the heating assembly of the first module positioned adjacent to a second side of the plurality of process chambers opposite the first side when the housing is received in the bay</p>	<p>In the accused workflow extracting the nucleic acids comprises removably receiving a housing comprising a plurality of process chambers in the bay, the plurality of process chambers maintained at a same height relative to one another as the housing is received in and removed from the bay, the plurality of process chambers aligned along a first axis when the housing is received in the bay, the bay comprising one or more complementary registration members that receive the housing in a single orientation when the housing is received in the bay, the magnetic separator of the first module positioned to apply a magnetic force to a first side of the plurality of process chambers when the housing is received in the bay, the magnetic separator comprising one or more magnets aligned along a second axis parallel to the first axis when the housing is received in the bay, the one or more complementary registration members aligning the plurality of process chambers with the magnetic separator when the housing is received in the bay, the heating assembly of the first module positioned adjacent to a second side of the plurality of process chambers opposite the first side when the housing is received in the bay.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the

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		<p>excess solution flowing into a self-contained waste chamber.” <i>Id.</i> at 2:28-2:39.</p> <ul style="list-style-type: none"> <li data-bbox="615 272 1228 305">• <i>Id.</i> at 2:28 (showing lysate in the s-channel).  <ul style="list-style-type: none"> <li data-bbox="615 857 1913 1036">• “A precise volume of air is then applied to remove any remaining liquid into the waste chamber. NeuMoDx wash solution is pumped via the fluid port into the microfluidic cartridge to remove all unbound material, followed by another volume of air to remove excess wash solution. High pH NeuMoDx release reagent is dispensed into the s-channel to cover the beads, and heat is applied to the denaturation process, resulting in released nucleic acid or eluate.” <i>Id.</i> at 2:39-3:12. <p>On information and belief, in the accused system extracting the nucleic acids comprises removably receiving a housing comprising a plurality of process chambers in the bay, the plurality of process chambers maintained at a same height relative to one another as the housing is received in and removed from the bay, the plurality of process chambers aligned along a first axis when the housing is received in the bay, the bay comprising one or more complementary registration members that receive the housing in a single orientation when the housing is received in the bay, the magnetic separator of the first module positioned to apply a magnetic force to a first side of the plurality of process chambers when the housing is received in the bay, the magnetic separator comprising one or more magnets aligned along a second axis parallel to the first axis when the housing is received in the bay, the one or more complementary</p>

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		<p>registration members aligning the plurality of process chambers with the magnetic separator when the housing is received in the bay, the heating assembly of the first module positioned adjacent to a second side of the plurality of process chambers opposite the first side when the housing is received in the bay.</p> <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> • Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate. • Claim 11. The cartridge of claim 10, further comprising 1) a heating region defined as a recessed region of the first layer that is parallel to the set of voids of the corrugated surface, and 2) a vent region, such that the first fluidic pathway is configured to cross the heating region and to pass through the vent region upstream of the first detection chamber, and the second fluidic pathway is configured to cross the heating region and to pass through the vent region upstream of the second detection chamber. • U.S. Patent No. 9,403,165 at 3:27-32 (“As shown in FIGS. 1B and 1C, the top layer 110 preferably comprises a set of sample port-reagent port pairs 112, a fluid port 118, a vent region 190, a heating region 195 crossing a capture segment 166 of a fluidic pathway 165, and a set of detection chambers 116.”) • U.S. Patent No. 9,403,165 at 1A.

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		 <p data-bbox="1050 909 1218 950">FIG. 1A</p> <ul data-bbox="609 950 1155 982" style="list-style-type: none"> • U.S. Patent No. 9,403,165 at FIG. 1B  <p data-bbox="1018 1234 1186 1274">FIG. 1B</p> <ul data-bbox="609 1274 1155 1307" style="list-style-type: none"> • U.S. Patent No. 9,403,165 at FIG. 1C .

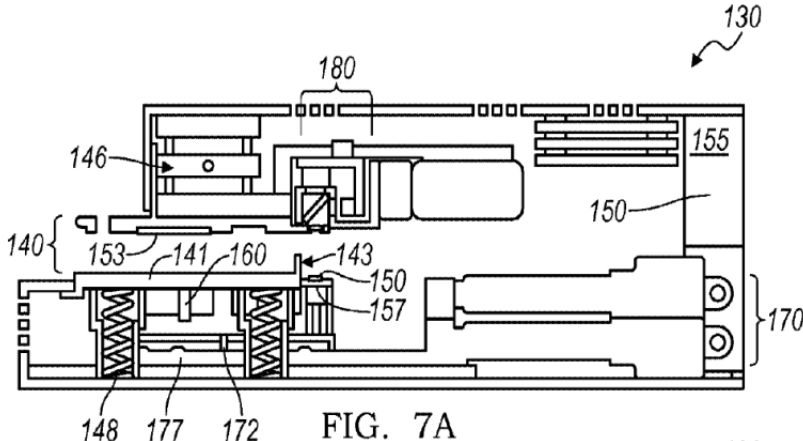
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		 <p>FIG. 1C</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,403,165 at 12:45-49 (“In an embodiment of the microfluidic cartridge 100 comprising a bottom layer 170, the magnet housing region 150 may further be defined by the bottom layer 170, such that the bottom layer partially forms a boundary of the magnet housing region 150.”) • U.S. Patent No. 9,403,165 at 13:40-47 (“Furthermore, at least one fluidic pathway 165 in the set of fluidic pathways 160 is preferably configured to be occluded upon deformation of the elastomeric layer 140, configured to transfer a waste fluid to the waste chamber 30, comprises a capture segment 166 passing through the heating region 195 and a magnetic field 156, and is configured to pass through the vent region 190 upstream of a detection chamber 117.”) • U.S. Patent No. 9,403,165 at 14:39-50 (“As shown in FIGS. 1C, 6C, 7 and 9, a fluidic pathway 165 of the set of fluidic pathways 160 is branched and preferably comprises an initial segment 174 fluidically coupled to a fluid channel 119 coupled to a fluid port 118, a sample segment 175 coupled to a sample port 114, a reagent segment 176 coupled to a reagent port 115, a capture segment 166 passing through at least one of the heating region 195 and a magnetic field 156, a vent segment 177 configured to pass through the vent region 190, a segment running to a detection chamber 163, a segment running away from the detection chamber 164, and at least one waste segment 178, 179 configured to transfer a waste fluid to a waste chamber 130.”) • U.S. Patent No. 9,403,165 at 16:58-17:5 (“As shown in FIG. 1H, the first and the fourth occlusion positions 142, 145 may then be occluded to form a sixth truncated pathway sealing the volume of release solution, with the captured magnetic beads bound to nucleic acids, within the capture segment 166. The volume of the remaining release solution is therefore substantially defined by the microchannel volume between junctions in the fluidic pathway 165 near the fourth and sixth

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		<p>occlusion positions 145, 147, and may be any small volume but in a specific variation is precisely metered to be 23+/-1 microliters. Release solution may be sealed within capture segments of other fluidic pathways using a similar process. A heater may then be provided at the sixth truncated pathway, inducing a pH shift within the sixth truncated pathway to unbind nucleic acids from the magnetic beads.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at 21:17-32 (“Multiple fluidic pathways may be configured to pass through a single heating region 195 of the microfluidic cartridge 100, a single vent region 190 of the microfluidic cartridge 100, and/or a magnetic field 156 produced by a magnet 152 housed within a single magnet housing region 150. Preferably all fluidic pathways of the set of fluidic pathways 160 are configured to pass through a single heating region 195 of the microfluidic cartridge 100, a single vent region 190 of the microfluidic cartridge 100, and a magnetic field 156 produced by a magnet 152 housed within a single magnet housing region 150; however, alternative embodiments of the set of fluidic pathways 160 of the microfluidic cartridge may comprise different configurations wherein fluidic pathways of the set of fluidic pathways 160 do not share a single heating region 195, a single vent region 190, and/or a magnetic field 156.”) <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of

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		<p>the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> Patent No. 9,382,532 at 9:31-49 (“ In some variations, Step S160 can further comprise Step S161, which recites heating the moiety-bound nucleic acid volume. Step S161 functions to provide additional environmental conditions that facilitate release of the nucleic acid sample from the microparticles, and can further function to mitigate effects of proteolytic enzymes that are used in Steps S110, S120, and/or S130 or that may be released from the biological sample containing the nucleic acid. Preferably, an elevated temperature in combination with an elevated pH resulting from the elution solution provides the enhanced conditions to facilitate the release of the nucleic acid sample. Furthermore, an elevated temperature (e.g., elevating a sample eluted at room temperature to 85 C) can function to minimize protease enzyme activity in the eluted nucleic acid and thereby improve the robustness of the detection of the target nucleic acid sample during processing in variations of Step S110; however, the method 100 can alternatively omitt Step S161 in applications wherein heating the moiety-bound nucleic acid volume is undesirable and/or unnecessary.”) Patent No. 9,382,532 at 13:42-60 (“A first example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, cerebrospinal fluid (CSF) as a representative biological sample, and Enterovirus (EV) viral particles as the model target. In the first example, 200 µL of CSF was spiked with 2 uL of EV viral particle lysate and then mixed with 500 µL of RNA Collection Buffer 1 (CBR-1) and 300 µL of nuclease-free water in examples of Steps S110 and S120. As a comparison, a similar amount of EV particle lysate was spiked into a 1 mL solution comprised of 500 µL of CBR-1 buffer and 500 µL of nuclease-free water and processed simultaneously. In an example of Step S130, RNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 60 C. Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2×) with 500 µL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) <i>See also id.</i> at 14:5-23, 14:41-59, 15:8-24, 15:58-16:12, 16:29-44, 16:61-17:10, 17:27-43, 17:60-18:14, 18:31-47, 19:12-27, 19:46-61, 20:7-23, 20:33-50, 21:23-39, 21:59-22:8, 22:31-49.

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		<ul style="list-style-type: none"> Patent No. 9,382,532 at 24:1-12 (“A first illustration of the eighteenth example, as shown in FIG. 22A, of a fluidic pathway 165 preferably comprises an initial segment 174 fluidically coupled to a fluid channel 119 coupled to a shared fluid port 118, a sample segment 175 coupled to a sample port 114 and to the initial segment 174, and an s-shaped capture segment 166, configured to pass through the heating region 195 and a magnetic field 156, coupled to the initial segment 174 and the sample segment 175. In an alternative illustration of the eighteenth example, the s-shaped capture segment 166 may comprise an initial wide arc 166 to provide a greater surface area for magnetic bead capture.”) Patent No. 9,382,532 at 25:47-50 (“A heater may then be provided at the sixth truncated pathway, inducing a pH shift within the sixth truncated pathway to unbind nucleic acids from the magnetic beads.”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. Claim 12. The system of claim 1, wherein the molecular diagnostic module further comprises a molecular diagnostic module heater configured to heat at least one magnetic bead-sample. Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume

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		<p>to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) • U.S. Patent No. 9,050,594 at FIG. 7A

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		 <p data-bbox="1031 667 1167 699">FIG. 7A</p> <ul data-bbox="615 708 1925 1401" style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 10:29-43 (“The heating and cooling subsystem 150 of the molecular diagnostic module 130 comprises a cartridge heater 153, a fan 155, and a set of detection chamber heaters 157 and functions to controllably heat portions of a microfluidic cartridge 210 for processing of a biological sample containing nucleic acids according to a molecular diagnostic protocol. In the orientation of an embodiment of the molecular diagnostic module 130 shown in FIGS. 7A-7C, the cartridge heater 153 is preferably coupled to the linear actuator 146 of the cartridge receiving module 140 and configured to span a central region of a microfluidic cartridge 210 aligned within the molecular diagnostic module 130, the fan 155 is located at a back wall of the cartridge receiving module 140, and the set of detection chamber heaters 157 is located inferior to a set of detection chambers 213 of the microfluidic cartridge 210.”) • U.S. Patent No. 9,050,594 at 10:49-56 (“The cartridge heater 153 functions to transfer heat to a heating region 224 of a microfluidic cartridge 210, for inducing a pH shift to release bound nucleic acids from magnetic beads within the heating region 224. The cartridge heater 153 is preferably a plate-shaped heater configured to transfer heat to the microfluidic cartridge 210 only from one side of the cartridge heater 153, such that heat flows through one face of the plate-shaped heater to the microfluidic cartridge 210.”) • U.S. Patent No. 9,050,594 at 11:13-32 (“Preferably, the cartridge heater 153 is configured to linearly translate with the linear actuator 146 of the cartridge receiving module 140, in order

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		<p>to align with a heating region 224 spanning a central portion of a microfluidic cartridge 210 aligned within the molecular diagnostic module 130. In one variation, the cartridge heater 153 is preferably fixed relative to the linear actuator 146 such that (in the orientation shown in FIGS. 7B-7C), the cartridge heater 153 can only move vertically with the linear actuator. In an alternative variation, the cartridge heater 153 may additionally be configured to translate laterally with a horizontal plane (in the orientation shown in FIGS. 7B-7C), such that the cartridge heater 153 can translate in at least two perpendicular coordinate planes. In this alternative variation, the cartridge heater 153 can be configured to sweep across a surface of a microfluidic cartridge 210 aligned within the molecular diagnostic module 130, or to translate in response to motion of the microfluidic cartridge 210, such that the position of the cartridge heater 153 relative to a heating region 224 of the microfluidic cartridge 210 is always fixed.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 22:47-60 (“Furthermore, in the embodiment, the top layer 211 of the microfluidic cartridge 210 further comprises a shared fluid port 222, a vent region 223, and a heating region 224, such that each fluidic pathway 220 in the set of fluidic pathways 219 is fluidically coupled to a sample port-reagent port pair 224, the shared fluid port 222, the waste chamber 216, and a detection chamber 225, comprises a turnabout portion 226 configured to pass through the heating region 224 and the magnetic field, and is configured to pass through the vent region 223 upstream of the detection chamber 225. Each fluidic pathway 220 thus functions to receive and facilitate processing of a sample fluid containing nucleic acids as it passes through different portions of the fluidic pathway 220.”) • U.S. Patent No. 9,050,594 at 29:5-13 (“Step S430 may further comprise occluding at least one fluidic pathway of the set of fluidic pathways at a subset of a set of occlusion positions S432, which functions to define at least one truncated fluidic pathway. Preferably, Step S432 comprises defining at least one truncated fluidic pathway passing through at least one of a heating region and a magnetic field; however, Step S432 may alternatively not comprise defining a truncated fluidic pathway passing through at least one of a heating region and a magnetic field.”)
1(k)	the heater assembly comprising one or more heaters aligned along a third axis parallel to the	In the accused workflow extracting the nucleic acids comprises removably receiving a housing comprising a plurality of process chambers in the bay, the plurality of process chambers maintained at a same height relative to one another as the housing is received in and removed from the bay, the plurality of process chambers aligned along a first axis when the housing is received in the bay, the bay comprising

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	first axis when the housing is received in the bay	<p>one or more complementary registration members that receive the housing in a single orientation when the housing is received in the bay, the magnetic separator of the first module positioned to apply a magnetic force to a first side of the plurality of process chambers when the housing is received in the bay, the magnetic separator comprising one or more magnets aligned along a second axis parallel to the first axis when the housing is received in the bay, the one or more complementary registration members aligning the plurality of process chambers with the magnetic separator when the housing is received in the bay, the heating assembly of the first module positioned adjacent to a second side of the plurality of process chambers opposite the first side when the housing is received in the bay, the heater assembly comprising one or more heaters aligned along a third axis parallel to the first axis when the housing is received in the bay.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” <i>Id.</i> at 2:28-2:39. • <i>Id.</i> at 2:28 (showing lysate in the s-channel).

Claim	Claim Language	Infringement Evidence
		<div data-bbox="659 228 1619 771" data-label="Image"> </div> <ul style="list-style-type: none"> <p>“A precise volume of air is then applied to remove any remaining liquid into the waste chamber. NeuMoDx wash solution is pumped via the fluid port into the microfluidic cartridge to remove all unbound material, followed by another volume of air to remove excess wash solution. High pH NeuMoDx release reagent is dispensed into the s-channel to cover the beads, and heat is applied to the denaturation process, resulting in released nucleic acid or eluate.” <i>Id.</i> at 2:39-3:12.</p> <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> <p>Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of</p>

Claim	Claim Language	Infringement Evidence
		<p>pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> Patent No. 9,382,532 at 10:3-13 (“In the variation of the specific example, the microparticles of the moiety-bound nucleic acid volume can be retained by a magnetic field within a portion of the fluidic pathway upon occlusion of the fluidic pathway at a suitable set of occlusion positions, and the elution solution can be delivered through the portion of the fluidic pathway enable release of the nucleic acid sample from the microparticle. Additionally, a heating element of the system can be moved proximal to the portion of the fluidic pathway with the elution solution and the microparticles to further enhance release of the nucleic acid sample.”) Patent No. 9,382,532 at 24:1-12 (“A first illustration of the eighteenth example, as shown in FIG. 22A, of a fluidic pathway 165 preferably comprises an initial segment 174 fluidically coupled to a fluid channel 119 coupled to a shared fluid port 118, a sample segment 175 coupled to a sample port 114 and to the initial segment 174, and an s-shaped capture segment 166, configured to pass through the heating region 195 and a magnetic field 156, coupled to the initial segment 174 and the sample segment 175. In an alternative illustration of the eighteenth example, the s-shaped capture segment 166 may comprise an initial wide arc 166 to provide a greater surface area for magnetic bead capture.”) <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and

Claim	Claim Language	Infringement Evidence
		<p>formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate.</p> <ul style="list-style-type: none"> • Claim 10. The cartridge of claim 8, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the second detection chamber, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port. • Claim 11. The cartridge of claim 10, further comprising 1) a heating region defined as a recessed region of the first layer that is parallel to the set of voids of the corrugated surface, and 2) a vent region, such that the first fluidic pathway is configured to cross the heating region and to pass through the vent region upstream of the first detection chamber, and the second fluidic pathway is configured to cross the heating region and to pass through the vent region upstream of the second detection chamber. • U.S. Patent No. 9,403,165 at 3:27-32 (“As shown in FIGS. 1B and 1C, the top layer 110 preferably comprises a set of sample port-reagent port pairs 112, a fluid port 118, a vent region 190, a heating region 195 crossing a capture segment 166 of a fluidic pathway 165, and a set of detection chambers 116.”) • U.S. Patent No. 9,403,165 at 1A.



Claim	Claim Language	Infringement Evidence
		<div data-bbox="682 235 1591 917"> </div> <p data-bbox="1056 911 1209 946">FIG. 1A</p> <ul data-bbox="615 954 1157 987" style="list-style-type: none"> • U.S. Patent No. 9,403,165 at FIG. 1C . <div data-bbox="682 1011 1577 1323"> <p data-bbox="1050 1263 1203 1299">FIG. 1C</p> </div> <ul data-bbox="615 1339 1921 1411" style="list-style-type: none"> • U.S. Patent No. 9,403,165 at 14:39-50 (“As shown in FIGS. 1C, 6C, 7 and 9, a fluidic pathway 165 of the set of fluidic pathways 160 is branched and preferably comprises an initial segment 174


Claim	Claim Language	Infringement Evidence
		<p>fluidically coupled to a fluid channel 119 coupled to a fluid port 118, a sample segment 175 coupled to a sample port 114, a reagent segment 176 coupled to a reagent port 115, a capture segment 166 passing through at least one of the heating region 195 and a magnetic field 156, a vent segment 177 configured to pass through the vent region 190, a segment running to a detection chamber 163, a segment running away from the detection chamber 164, and at least one waste segment 178, 179 configured to transfer a waste fluid to a waste chamber 130.”)</p> <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 12. The system of claim 1, wherein the molecular diagnostic module further comprises a molecular diagnostic module heater configured to heat at least one magnetic bead-sample. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway

Claim	Claim Language	Infringement Evidence
		<p>configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) • U.S. Patent No. 9,050,594 at 2:49-58 (“As shown in FIGS. 1A-1B and 7A, an embodiment of a system 100 for processing and detecting nucleic acids comprises: a capture plate 110 configured to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119; a molecular diagnostic module 130 comprising a microfluidic cartridge receiving module 140, heating and cooling subsystem 150, a magnet 160, a valve actuation subsystem 170, an optical subsystem 180; and an assay strip 190 configured to facilitate mixing of molecular diagnostic reagents with a nucleic acid volume.”) • U.S. Patent No. 9,050,594 at FIG. 7A

Claim	Claim Language	Infringement Evidence
		<div data-bbox="716 256 1514 699" data-label="Image"> </div> <p data-bbox="1031 667 1167 699">FIG. 7A</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 10:49-65 (“The cartridge heater 153 functions to transfer heat to a heating region 224 of a microfluidic cartridge 210, for inducing a pH shift to release bound nucleic acids from magnetic beads within the heating region 224. The cartridge heater 153 is preferably a plate-shaped heater configured to transfer heat to the microfluidic cartridge 210 only from one side of the cartridge heater 153, such that heat flows through one face of the plate-shaped heater to the microfluidic cartridge 210. In a specific example, the cartridge heater 153 is a silicon wafer etched to be conductive and form a resistance heater. In the preferred variation, the cartridge heater 153 is either flip-chip bonded (i.e., soldered to back side of a circuit board), or wire bonded to a circuit board, and then coupled using linear bearings and springs to a plate coupled to the linear actuator 146. The preferred variation allows independent control of 12 independent channels, corresponding to 12 different pathways for sample processing.”) U.S. Patent No. 9,050,594 at 13:6-12 (“In an example, as shown in FIGS. 7A-7C, the magnet 160 is a rectangular prism-shaped magnet 160 fixed under the cartridge platform 141, and configured to pass through the cartridge platform 141, into a magnet housing region 218 located under the heating region 224 of the microfluidic cartridge 210.”) U.S. Patent No. 9,050,594 at 22:61-23:5 (“The microfluidic cartridge 210 is preferably configured to be received and manipulated by the molecular diagnostic module 130, such that the cartridge receiving module 140 of the molecular diagnostic module 130 receives and aligns the microfluidic cartridge 210 within the molecular diagnostic module 130, the heating and cooling subsystem

Claim	Claim Language	Infringement Evidence
		<p>150 of the molecular diagnostic module 130 is configured to transfer heat to the heating region 224 of the microfluidic cartridge 210, and the magnet 160 of the molecular diagnostic module 130 is configured to be received by the magnet housing region 218 of the microfluidic cartridge 210 to provide a magnetic field for separation of nucleic acids.”)</p>
1(l)	<p>the one or more complementary registration members aligning the plurality of process chambers with the heater assembly when the housing is received in the bay</p>	<p>In the accused workflow extracting the nucleic acids comprises removably receiving a housing comprising a plurality of process chambers in the bay, the plurality of process chambers maintained at a same height relative to one another as the housing is received in and removed from the bay, the plurality of process chambers aligned along a first axis when the housing is received in the bay, the bay comprising one or more complementary registration members that receive the housing in a single orientation when the housing is received in the bay, the magnetic separator of the first module positioned to apply a magnetic force to a first side of the plurality of process chambers when the housing is received in the bay, the magnetic separator comprising one or more magnets aligned along a second axis parallel to the first axis when the housing is received in the bay, the one or more complementary registration members aligning the plurality of process chambers with the magnetic separator when the housing is received in the bay, the heating assembly of the first module positioned adjacent to a second side of the plurality of process chambers opposite the first side when the housing is received in the bay, the heater assembly comprising one or more heaters aligned along a third axis parallel to the first axis when the housing is received in the bay, the one or more complementary registration members aligning the plurality of process chambers with the heater assembly when the housing is received in the bay.</p> <p><i>NeuMoDx Molecular N288 System</i>, http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ TECHNOLOGY” hyperlink at https://player.vimeo.com/video/281470603. (Exhibit 17)</p> <ul style="list-style-type: none"> • At 4:17 (showing a plurality of multi-lane microfluidic cartridges in a plurality of receiving bays)

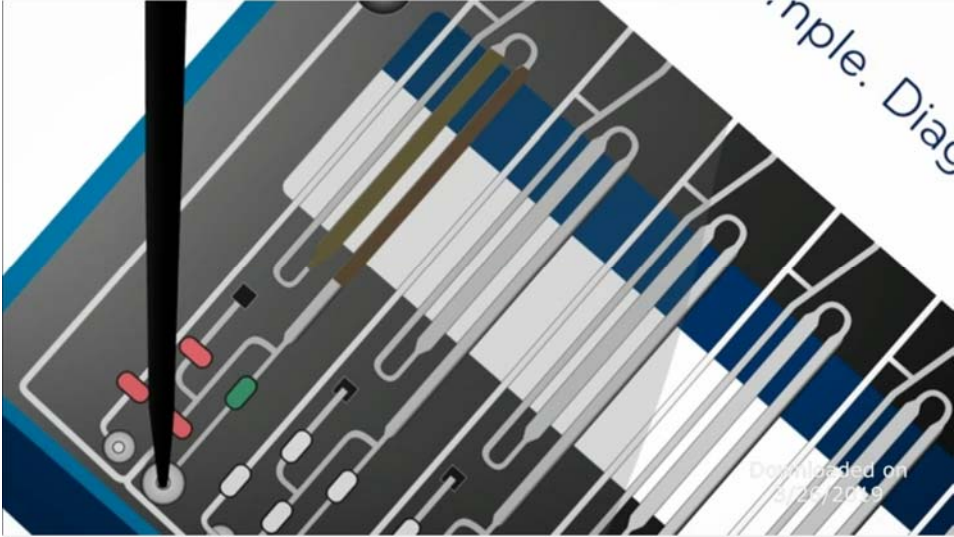
Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none">• at 4:55-5:00 (showing a plurality of multi-lane microfluidic cartridges in a plurality of receiving bays) 


Claim	Claim Language	Infringement Evidence
		<div data-bbox="569 264 1633 561">  </div> <p data-bbox="569 638 884 670">US9050594 (Exhibit 24)</p> <ul data-bbox="615 678 1921 1409" style="list-style-type: none"> <li data-bbox="615 678 1921 1117">• Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. <li data-bbox="615 1122 1921 1190">• Claim 12. The system of claim 1, wherein the molecular diagnostic module further comprises a molecular diagnostic module heater configured to heat at least one magnetic bead-sample. <li data-bbox="615 1195 1921 1409">• Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the


Claim	Claim Language	Infringement Evidence
		<p>magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at 8:60-9:15 (“The linear actuator 146 functions to linearly displace a microfluidic cartridge 210 resting on the cartridge platform 141, in order to compress the microfluidic cartridge 210 and position the microfluidic cartridge 210 between a cartridge heater 153 and an optical subsystem 180 on one side of the microfluidic cartridge 210, and a magnet 160 and detection chamber heaters 157 on another side of the microfluidic cartridge 210. The linear actuator 146 also functions to provide a sufficient counterforce to the valve actuation subsystem 170 such that a microfluidic cartridge 210 within the molecular diagnostic module 130 remains properly situation upon manipulation by the valve actuation subsystem 170. The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210. In the orientation of the molecular diagnostic module 130 shown in FIGS. 7B and 7B, the linear actuator 146 is preferably coupled to a portion of the heating and cooling subsystem 150 a portion of the optical subsystem 180, and the nozzle 149, and vertically displaces the cartridge heater 153, the optical subsystem 180, and the nozzle 149 to position the cartridge heater 153, 180 and the nozzle 149 over the microfluidic cartridge 210.”) • U.S. Patent No. 9,050,594 at FIG. 7A


Claim	Claim Language	Infringement Evidence
		<div data-bbox="716 256 1514 699" data-label="Image"> </div> <p data-bbox="1031 667 1167 699">FIG. 7A</p> <ul style="list-style-type: none"> <li data-bbox="615 708 1923 1247"> <p>U.S. Patent No. 9,050,594 at 10:5-26 (“Similarly, the nozzle 149, the heating and cooling subsystem 150, the cartridge heater 153, and the magnet 160 are preferably coupled to springs, such that springs are positioned between elements 149, 150, 153, and 160, and substrates that elements 149, 150, 153, and 160 are mounted to. Alternatively an elastomeric material is preferably positioned between elements 149, 150, 153, and 160, and substrates that elements 149, 150, 153, and 160 are mounted to. The springs and/or elastomeric material function to provide proper functioning and alignment of subsystems of the molecular diagnostic module 130 as the linear actuator 146 is extended or retracted, contributing to reliability and a reduction in stack up tolerance risk. The springs and/or elastomeric material further function to allow more pressure to be applied to occlusion positions of a microfluidic cartridge 210 aligned within the molecular diagnostic module 130, and an appropriate pressure to be applied to elements 149, 150, 153 and 160 of the molecular diagnostic module 130. Thus, proper contact is maintained between elements 149, 150, 153, and 160, and a microfluidic cartridge 210 being manipulated by the molecular diagnostic module. These elements are described in further detail below.”)</p> <li data-bbox="615 1255 1923 1398"> <p>U.S. Patent No. 9,050,594 at 10:29-48 (“The heating and cooling subsystem 150 of the molecular diagnostic module 130 comprises a cartridge heater 153, a fan 155, and a set of detection chamber heaters 157 and functions to controllably heat portions of a microfluidic cartridge 210 for processing of a biological sample containing nucleic acids according to a molecular diagnostic</p>

Claim	Claim Language	Infringement Evidence
		<p>protocol. In the orientation of an embodiment of the molecular diagnostic module 130 shown in FIGS. 7A-7C, the cartridge heater 153 is preferably coupled to the linear actuator 146 of the cartridge receiving module 140 and configured to span a central region of a microfluidic cartridge 210 aligned within the molecular diagnostic module 130, the fan 155 is located at a back wall of the cartridge receiving module 140, and the set of detection chamber heaters 157 is located inferior to a set of detection chambers 213 of the microfluidic cartridge 210. In alternative embodiments of the molecular diagnostic module 130, the heating and cooling subsystem 150 may have any appropriate alternative configuration that provides controlled heating and cooling to a microfluidic cartridge within the molecular diagnostic module 130.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 11:13-32 (“Preferably, the cartridge heater 153 is configured to linearly translate with the linear actuator 146 of the cartridge receiving module 140, in order to align with a heating region 224 spanning a central portion of a microfluidic cartridge 210 aligned within the molecular diagnostic module 130. In one variation, the cartridge heater 153 is preferably fixed relative to the linear actuator 146 such that (in the orientation shown in FIGS. 7B-7C), the cartridge heater 153 can only move vertically with the linear actuator. In an alternative variation, the cartridge heater 153 may additionally be configured to translate laterally with a horizontal plane (in the orientation shown in FIGS. 7B-7C), such that the cartridge heater 153 can translate in at least two perpendicular coordinate planes. In this alternative variation, the cartridge heater 153 can be configured to sweep across a surface of a microfluidic cartridge 210 aligned within the molecular diagnostic module 130, or to translate in response to motion of the microfluidic cartridge 210, such that the position of the cartridge heater 153 relative to a heating region 224 of the microfluidic cartridge 210 is always fixed.”)
1(m)	moving the liquid dispenser between the plurality of nucleic acid-containing samples and the plurality of process chambers when the housing is received in the bay	<p>The accused workflow comprises moving the liquid dispenser between the plurality of nucleic acid-containing samples and the plurality of process chambers when the housing is received in the bay.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “The liquid handling robot delivers lysis buffer and patient specimen to the extraction plate, which has 24 independent wells which contain NeuDry affinity-coated paramagnetic beads. Each mixture is aspirated and dispensed five times to ensure homogeneity of the solution. Each

Claim	Claim Language	Infringement Evidence
		<p>extraction plate well is then heated independently for 10 minutes to ensure proper lysing and binding of the nucleic acids to the paramagnetic beads.” <i>Id.</i> 0:28-1:16.</p> <ul style="list-style-type: none"> • “Liquid Handling Processing B: Extraction. After thoroughly mixing the solution in each well of the extraction plate, the crude lysate is independently aspirated from each well and transferred to the NeuMoDx cartridge.” <i>Id.</i> 1:35-1:51. • “The liquid handling robot employs total aspiration and dispense monitoring pressure sensing to ensure each tip is securely seated into one of the 12 independent sample ports or s-ports of the cartridge. Once the pipette tip is secured, the entire volume of solution will be dispensed. Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber” <i>Id.</i> at 2:02-2:39. • <i>Id.</i> at 1:28 (showing dispensing of the mixture of nucleic acids and paramagnetic beads at the s-  <p>port).</p> <p><i>NeuMoDx Molecular N288 System</i>, http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ TECHNOLOGY” hyperlink at https://player.vimeo.com/video/281470603. (Exhibit 17)</p> <ul style="list-style-type: none"> • At 2:30 (showing a liquid dispenser at an extraction plate)

Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none">• At 3:10 (showing al liquid dispenser at a sample tube)

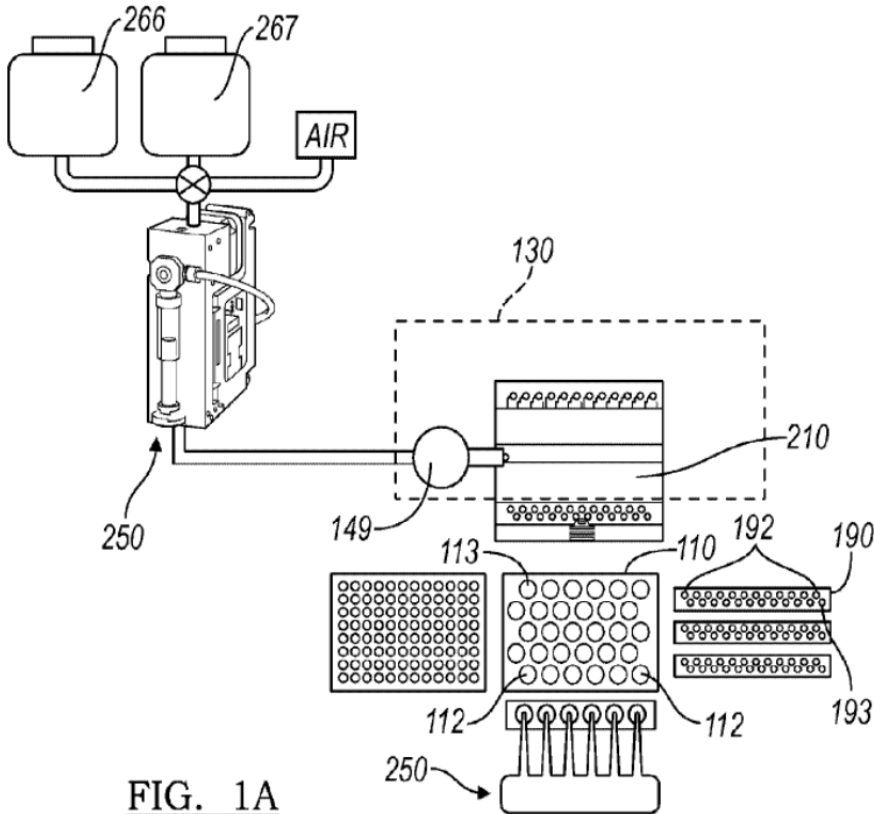
Claim	Claim Language	Infringement Evidence
		 <p>Downloaded on 3/26/2019</p> <ul style="list-style-type: none">• At 4:17 (showing the liquid dispenser at the microfluidic cartridge)

Claim	Claim Language	Infringement Evidence
		 <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> • Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position of the fluidic pathway, by way of the void of the corrugated surface, the fluidic pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber. • Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a

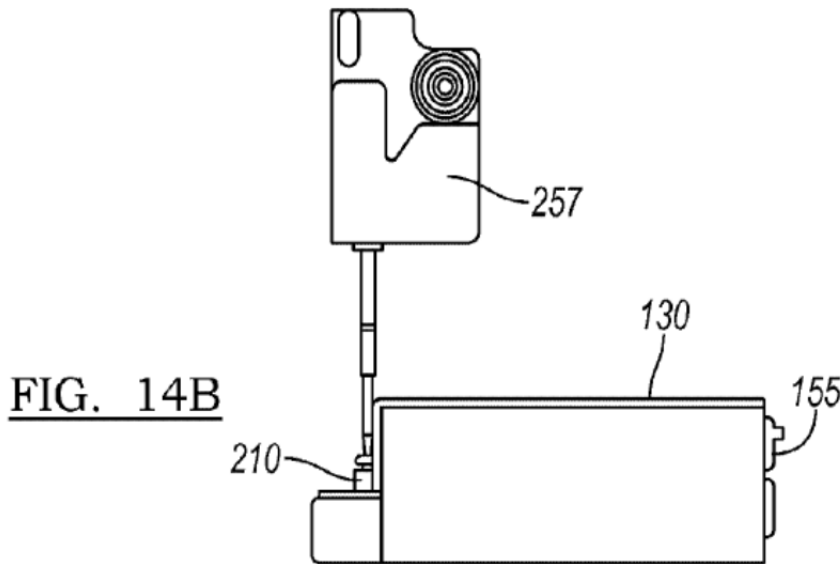
Claim	Claim Language	Infringement Evidence
		<p>film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate.</p> <ul style="list-style-type: none"> • Claim 10. The cartridge of claim 8, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the second detection chamber, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port. • U.S. Patent No. 9,403,165 at 3:32-52 (“Each sample-port-reagent port pair 113 of an embodiment of the top layer 110 comprises a sample port 114 and a reagent port 115. The sample port 114 functions to receive a volume of a sample fluid potentially containing the nucleic acids of interest for delivery of the volume of fluid to a portion of a fluidic pathway 165 coupled to the sample port-reagent port pair 113. In a specific embodiment, the volume of a sample fluid is a biological sample with magnetic beads for nucleic acid isolation; however, the volume of fluid comprising a sample fluid may alternatively be any appropriate fluid containing a sample with nucleic acids. Preferably, each sample port 114 is isolated from all other sample ports, in order to prevent cross-contamination between samples of nucleic acids being analyzed. Additionally, each sample port 114 is preferably of an appropriate geometric size and shape to accommodate a standard-size pipette tip used to deliver the volume of a sample fluid without leaking. Alternatively, all or a portion of the sample ports 114 are configured to be coupled to fluid conduits or tubing that deliver the volume of a sample fluid.”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with

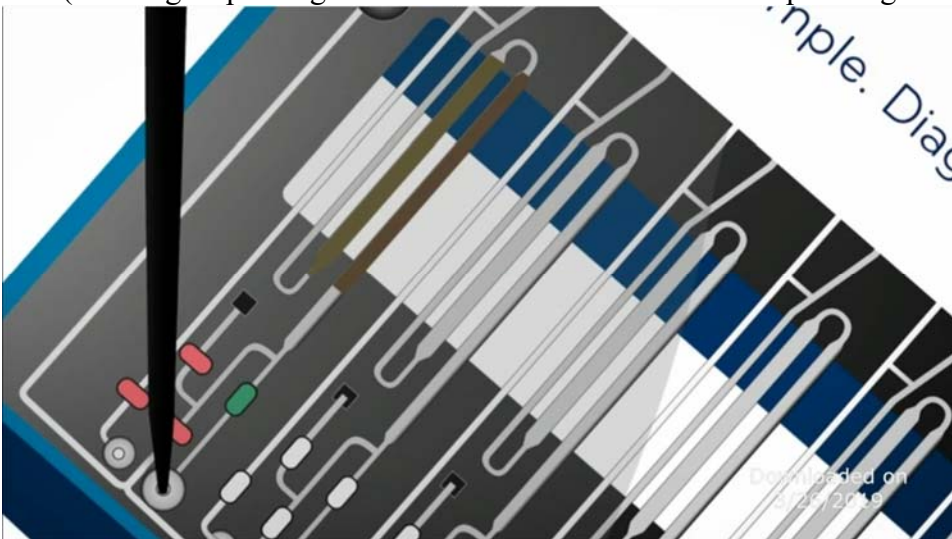
Claim	Claim Language	Infringement Evidence
		<p>a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • Claim 2. The system of claim 1, further comprising a liquid handling system configured to transfer at least one magnetic bead-sample from the capture plate to the molecular diagnostic module, and to aspirate at least one nucleic acid volume from the molecular diagnostic module. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module. • Claim 23. A system for processing and detecting nucleic acids, comprising: a molecular diagnostic module, configured to process a set of biological samples combined with magnetic beads and separate a set of nucleic acid volumes from the set of biological samples combined with magnetic


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		<p>beads, wherein the molecular diagnostic module comprises an actuator configured to displace a cartridge, a set of pins, and at least one cam contacting the set of pins, wherein an extension or retraction of the actuator moves the cartridge, and a displacement of a subset of the set of pins defines a set of pathways in the cartridge, each configured to receive a biological sample combined with magnetic beads of the set of biological samples combined with magnetic beads.</p> <ul style="list-style-type: none"> • Claim 24. The system of claim 23, further comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample, a lysing reagent, and a sample process control, wherein the capture plate facilitates production of at least one biological sample combined with magnetic beads; an assay strip comprising at least one reagent well containing a molecular diagnostic reagent volume configured to be combined with a nucleic acid volume of the set of nucleic acid volumes to produce at least one nucleic acid-reagent mixture; and a liquid handling system configured to transfer at least one biological sample combined with magnetic beads from the capture plate to the molecular diagnostic module, transfer at least one nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer at least one nucleic acid-reagent mixture from the assay strip back to the molecular diagnostic module. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) • U.S. Patent No. 9,050,594 at 2:49-3:1 (“As shown in FIGS. 1A-1B and 7A, an embodiment of a system 100 for processing and detecting nucleic acids comprises: a capture plate 110 configured to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119; a molecular diagnostic module 130 comprising a microfluidic cartridge receiving module 140, heating and cooling subsystem 150, a magnet 160, a valve actuation subsystem 170, an optical

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		<p>subsystem 180; and an assay strip 190 configured to facilitate mixing of molecular diagnostic reagents with a nucleic acid volume. Other embodiments of the system 100 may further comprise at least one of a capture plate module 120 configured to support the capture plate 110; a filter 200 and filter holder 205 to facilitate sample preparation; a microfluidic cartridge 210 configured to facilitate sample processing; an assay strip holder 230; an assay strip carrier 240; a liquid handling system 250 configured to facilitate gas and fluid delivery to different elements of the system 100; a processor configured to analyze data resulting from a run of the system 100; and a user interface configured to allow a user to interact with the system 100.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at FIG. 1A.  <p style="text-align: center;">FIG. 1A</p>

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		<ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 3:14-28 (“In one example workflow of the system 100, a liquid handling system 250 aspirates a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), and dispenses the set of biological samples into a capture plate 110 to be lysed and combined with magnetic beads (containing a proprietary affinity coating to bind the nucleic acids to the magnetic beads) by a capture plate module 120. The liquid handling system 250 then aspirates substantially all of each sample of the set of lysed biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate no [sic], and dispenses the set of magnetic bead-samples into a microfluidic cartridge 210, aligned within a cartridge receiving module 140 of a molecular diagnostic module 130, and configured to be manipulated by the molecular diagnostic module 130.”) U.S. Patent No. 9,050,594 at 23:28-53 (“The liquid handling system 250 of the system 100 includes a liquid handling arm 255 and a syringe pump 265, as shown in FIGS. 14A-14C and functions to deliver biological samples, reagents, and gases to elements of the system 100. As described in Section 1, an embodiment of the liquid handling system 250 is configured to aspirate a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), dispense the set of biological samples into a capture plate no [sic] to be lysed and combined with magnetic beads by a capture plate module 120, aspirate the set of biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate 110, and dispense the set of magnetic bead-samples into microfluidic cartridge 210 located in a molecular diagnostic module 130. The embodiment of the liquid handling system 100 is further configured to facilitate separation of a set of nucleic acids from the magnetic bead-samples, by dispensing a wash solution, a release solution, and/or air into the molecular diagnostic module 130, by the nozzle 149 coupled to the linear actuator 146, at appropriate stages, aspirate the set of nucleic acids from the molecular diagnostic module 130, combine the set of nucleic acids with a set of molecular diagnostic reagents using an assay strip 190, and dispense the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the molecular diagnostic module 130 for further processing and analysis.”) U.S. Patent No. 9,050,594 at FIG. 14B.

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		 <p>FIG. 14B</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 28:53-64 (“Step S430 recites transferring each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways, and functions to isolate each of the set of nucleic acid-magnetic bead samples within separate pathways for further processing. Preferably, all nucleic acid-magnetic bead samples in the set of nucleic acid-magnetic bead samples are transferred simultaneously to the set of fluidic pathways, but alternatively, each nucleic acid-magnetic bead sample in the set of magnetic bead-samples may be transferred to a corresponding fluidic pathway independently of the other nucleic acid-magnetic bead samples.”)
1(n)	dispensing, using the liquid dispenser, at least a portion of the plurality of nucleic acid-containing samples	<p>The accused workflow comprises dispensing, using the liquid dispenser, at least a portion of the plurality of nucleic acid-containing samples and a plurality of magnetic binding particles into the plurality of process chambers when the housing is received in the bay.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM),</p>

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	and a plurality of magnetic binding particles into the plurality of process chambers when the housing is received in the bay	<p>http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “The liquid handling robot delivers lysis buffer and patient specimen to the extraction plate, which has 24 independent wells which contain NeuDry affinity-coated paramagnetic beads. Each mixture is aspirated and dispensed five times to ensure homogeneity of the solution. Each extraction plate well is then heated independently for 10 minutes to ensure proper lysing and binding of the nucleic acids to the paramagnetic beads.” <i>Id.</i> 0:28-1:16. • “Liquid Handling Processing B: Extraction. After thoroughly mixing the solution in each well of the extraction plate, the crude lysate is independently aspirated from each well and transferred to the NeuMoDx cartridge.” <i>Id.</i> 1:35-1:51. • “The liquid handling robot employs total aspiration and dispense monitoring pressure sensing to ensure each tip is securely seated into one of the 12 independent sample ports or s-ports of the cartridge. Once the pipette tip is secured, the entire volume of solution will be dispensed. Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber” <i>Id.</i> at 2:02-2:39. • <i>Id.</i> at 1:28 (showing dispensing of the mixture of nucleic acids and paramagnetic beads at the s-  <p>port).</p>

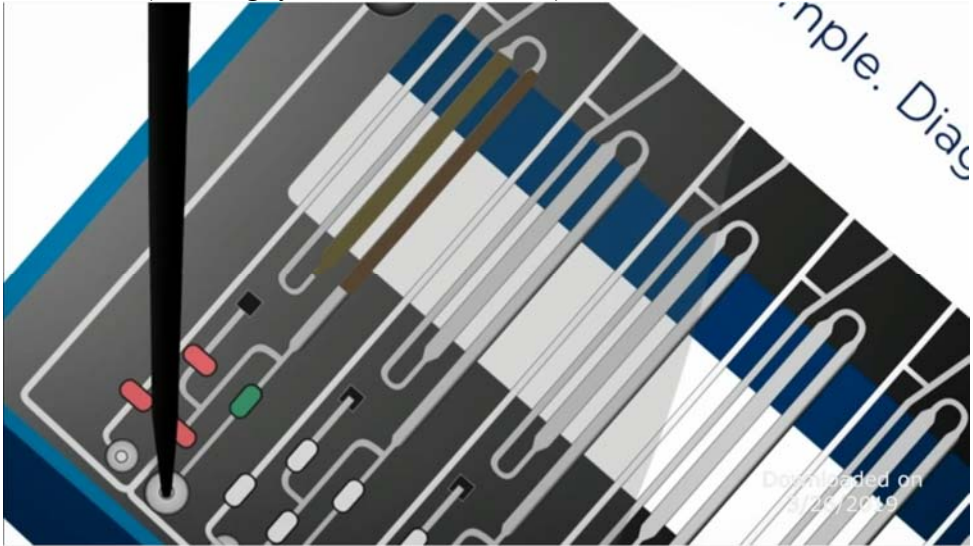
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		<p><i>NeuMoDx Molecular N288 System</i>, http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ TECHNOLOGY” hyperlink at https://player.vimeo.com/video/281470603. (Exhibit 17)</p> <ul style="list-style-type: none"> At 4:17 (showing the liquid dispenser at the microfluidic cartridge)  <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the

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		<p>actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • Claim 2. The system of claim 1, further comprising a liquid handling system configured to transfer at least one magnetic bead-sample from the capture plate to the molecular diagnostic module, and to aspirate at least one nucleic acid volume from the molecular diagnostic module. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module. • Claim 23. A system for processing and detecting nucleic acids, comprising: a molecular diagnostic module, configured to process a set of biological samples combined with magnetic beads and separate a set of nucleic acid volumes from the set of biological samples combined with magnetic beads, wherein the molecular diagnostic module comprises an actuator configured to displace a cartridge, a set of pins, and at least one cam contacting the set of pins, wherein an extension or retraction of the actuator moves the cartridge, and a displacement of a subset of the set of pins defines a set of pathways in the cartridge, each configured to receive a biological sample combined with magnetic beads of the set of biological samples combined with magnetic beads. • Claim 24. The system of claim 23, further comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample, a lysing

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		<p>reagent, and a sample process control, wherein the capture plate facilitates production of at least one biological sample combined with magnetic beads; an assay strip comprising at least one reagent well containing a molecular diagnostic reagent volume configured to be combined with a nucleic acid volume of the set of nucleic acid volumes to produce at least one nucleic acid-reagent mixture; and a liquid handling system configured to transfer at least one biological sample combined with magnetic beads from the capture plate to the molecular diagnostic module, transfer at least one nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer at least one nucleic acid-reagent mixture from the assay strip back to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 2:49-3:1 (“As shown in FIGS. 1A-1B and 7A, an embodiment of a system 100 for processing and detecting nucleic acids comprises: a capture plate 110 configured to facilitate binding of nucleic acids within a biological sample to a set of magnetic beads 119; a molecular diagnostic module 130 comprising a microfluidic cartridge receiving module 140, heating and cooling subsystem 150, a magnet 160, a valve actuation subsystem 170, an optical subsystem 180; and an assay strip 190 configured to facilitate mixing of molecular diagnostic reagents with a nucleic acid volume. Other embodiments of the system 100 may further comprise at least one of a capture plate module 120 configured to support the capture plate 110; a filter 200 and filter holder 205 to facilitate sample preparation; a microfluidic cartridge 210 configured to facilitate sample processing; an assay strip holder 230; an assay strip carrier 240; a liquid handling system 250 configured to facilitate gas and fluid delivery to different elements of the system 100; a processor configured to analyze data resulting from a run of the system 100; and a user interface configured to allow a user to interact with the system 100.”) • U.S. Patent No. 9,050,594 at FIG. 1A.

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		<p style="text-align: center;">FIG. 1A</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 3:20-28 (“The liquid handling system 250 then aspirates substantially all of each sample of the set of lysed biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate no [sic], and dispenses the set of magnetic bead-samples into a microfluidic cartridge 210, aligned within a cartridge receiving module 140 of a molecular diagnostic module 130, and configured to be manipulated by the molecular diagnostic module 130.”) U.S. Patent No. 9,050,594 at 23:28-41 (“The liquid handling system 250 of the system 100 includes a liquid handling arm 255 and a syringe pump 265, as shown in FIGS. 14A-14C and functions to deliver biological samples, reagents, and gases to elements of the system 100. As

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		<p>described in Section 1, an embodiment of the liquid handling system 250 is configured to aspirate a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), dispense the set of biological samples into a capture plate no [sic] to be lysed and combined with magnetic beads by a capture plate module 120, aspirate the set of biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate 110, and dispense the set of magnetic bead-samples into microfluidic cartridge 210 located in a molecular diagnostic module 130.")</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at FIG. 14B. <div data-bbox="667 578 1503 1138"> <p>FIG. 14B</p> </div> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 28:53-64 (“Step S430 recites transferring each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways, and functions to isolate each of the set of nucleic acid-magnetic bead samples within separate pathways for further processing. Preferably, all nucleic acid-magnetic bead samples in the set of nucleic acid-magnetic bead samples are transferred simultaneously to the set of fluidic pathways, but alternatively, each nucleic acid-magnetic bead sample in the set of magnetic bead-samples may be transferred to a corresponding

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		fluidic pathway independently of the other nucleic acid-magnetic bead samples.”)
1(o)	applying a magnetic force to the first side of the plurality of process chambers using the one or more magnets of the magnetic separator of the first module when the housing is received in the bay	<p>The accused workflow comprises applying a magnetic force to the first side of the plurality of process chambers using the one or more magnets of the magnetic separator of the first module when the housing is received in the bay.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” <i>Id.</i> at 2:28-2:39. • <i>Id.</i> at 2:28 (showing lysate in the s-channel).  <p>US9382532</p> <ul style="list-style-type: none"> • Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a

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		<p>set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 6. The method of claim 5, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety-sample mixture from the process chamber; occluding the fluidic pathway of the cartridge-at a set of occlusion positions upon displacement of pins of the set of pins to generate a path through a magnetic field, and to a waste chamber; and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber. • Claim 13. The method of claim 3, wherein releasing the nucleic acid sample from the set of moiety-bound nucleic acid particles comprises occluding the fluidic pathway of the cartridge, comprising the process chamber, at a set of occlusion positions, upon displacement of pins of the set of pins, to define a path through a magnetic field; delivering the set of moiety-bound nucleic acid particles into the path of the fluidic pathway; and delivering an elution solution into the fluidic pathway, thereby inducing a pH shift configured to release the nucleic acid sample from the set of moiety-bound nucleic acid particles. • Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and

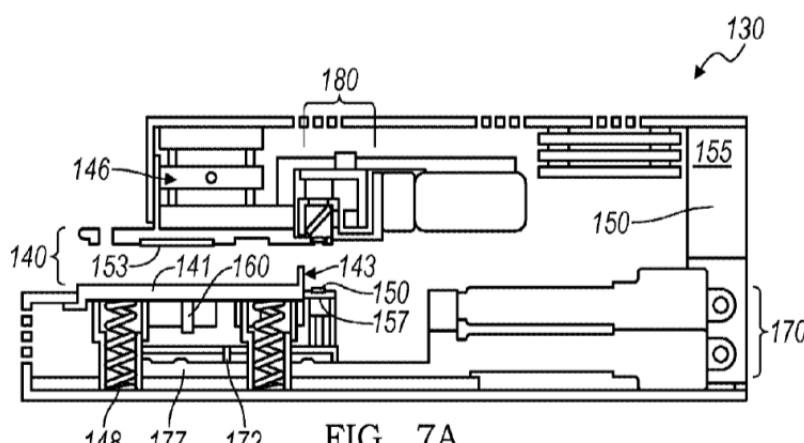
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		<p>concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second subset of the set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction.</p> <ul style="list-style-type: none"> • Claim 18. The method of claim 17, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety-sample mixture from the process chamber; occluding the fluidic pathway of the cartridge at a set of occlusion positions upon displacement of the first subset of the set of pins to generate a path through a magnetic field, and to a waste chamber of the cartridge; and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber. • Patent No. 9,382,532 at 6:46-59 (“Preferably, the moiety-bound nucleic acid volume is separated using a magnetic-separation method”; however the moiety-bound nucleic acid volume can alternatively be separated using methods based upon microparticle size, mass, and/or density (e.g., centrifugation, sedimenting, filtering), and/or focusing methods (e.g., electric field focusing, laser based focusing). Separation in Step S140 can, however, be performed using any other suitable method. In a first variation, wherein the microparticles coupled with affinity moieties

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		<p>have magnetic properties, a magnetic field can be applied to retain the nucleic acid-bound microparticles of the moiety-bound nucleic acid volume, while the waste volume (e.g., cellular debris and other unbound material) is substantially removed by aspiration.”)</p> <ul style="list-style-type: none"> Patent No. 9,382,532 at 8:48-55 (“In the variation of the first example, the microparticles of the moiety-bound nucleic acid volume can be retained by a magnetic field within a portion of the fluidic pathway upon occlusion of the fluidic pathway at a suitable set of occlusion positions, and the wash solution can be delivered through the portion of the fluidic pathway and into a waste chamber of the cartridge to wash the microparticles with the bound target nucleic acid(s).”) Patent No. 9,382,532 at 24:53-25:2 (“The occlusion positions of the set of occlusion positions 141 of the first illustration are preferably located such that occluding subsets of the set of occlusion positions 141 defines unique truncated fluidic pathways to controllably direct fluid flow. For example, as shown in FIG. 22B, occluding the fluidic pathway 165 at the first, third, fourth, and sixth occlusion positions 142, 144, 145, 147 forms a truncated pathway by which a volume of a sample fluid, comprising nucleic acids bound to magnetic beads and delivered into the sample port 114, may flow past the second occlusion positions 143 into the capture segment 166 for isolation and purification of nucleic acids using the heating region 195 and the magnetic field 156. Nucleic acids bound to magnetic beads may thus be trapped within the capture segment 166 by the magnetic field 156, while other substances in the volume of sample fluid may pass into the waste chamber 130 by passing the fifth occlusion position 146.”) <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position of the fluidic pathway, by way of the void of the corrugated surface, the fluidic pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber.

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		<ul style="list-style-type: none"> • Claim 3. The cartridge of claim 1, wherein the waste chamber comprises at least one waste inlet in communication with the opening of the intermediate substrate, and wherein the corrugated surface of the waste chamber further defines a rectangular prismatic void spanning a long dimension of the cartridge that defines a magnet housing region configured to reversibly receive a magnet from the direction perpendicular to a broad face of the first layer, and configured to cross the fluidic pathway. • Claim 4. The cartridge of claim 3, wherein the fluidic pathway comprises a capture segment, downstream of the sample port and configured to cross the magnet housing region multiple times. • Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate. • Claim 15. The cartridge of claim 8, wherein at least one void of the set of voids defined by the corrugated surface of the waste chamber is a rectangular prismatic void spanning a long dimension of the cartridge and defining a magnet housing region configured to cross the first fluidic pathway and the second fluidic pathway. • U.S. Patent No. 9,403,165 at 2:39-63 (“As shown in FIGS. 1A-1C, an embodiment of a microfluidic cartridge 100 for processing and detecting nucleic acids comprises: a top layer 110 comprising a set of sample port-reagent port pairs 112 and a set of detection chambers 116; an intermediate substrate 120, coupled to the top layer 110 and partially separated from the top layer by a film layer 125, configured to form a waste chamber 130; an elastomeric layer 140 partially situated on the intermediate substrate 120; a magnet housing region 150 accessible by a magnet 152 providing a magnetic field 156; and a set of fluidic pathways 160, each formed by at least a portion of the top layer 110, a portion of the film layer 125, and a portion of the elastomeric layer 140. In other embodiments, the microfluidic cartridge 100 may further comprise a bottom layer

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		<p>170 coupled to the intermediate substrate 120 and configured to seal the waste chamber 130. Furthermore, the top layer 110 of the microfluidic cartridge 100 may further comprise a shared fluid port 118, a vent region 190, and a heating region 195, such that each fluidic pathway 165 in the set of fluidic pathways 160 is fluidically coupled to a sample port-reagent port pair 113, the shared fluid port 118, the waste chamber 130, and a detection chamber 117, comprises a capture segment 166 configured to pass through the heating region and the magnetic field, and is configured to pass through the vent region 190 upstream of the detection chamber 117.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,403,165 at 12:38-58 (“The magnet housing region 150 of the microfluidic cartridge 100 functions to provide access to and/or house at least one magnet 152 providing a magnetic field 156 for purification and isolation of nucleic acids. Preferably, the magnet housing region 150 is defined by the film layer and the intermediate substrate, such that the film layer and the intermediate substrate form the boundaries of the magnet housing region 150. In an embodiment of the microfluidic cartridge 100 comprising a bottom layer 170, the magnet housing region 150 may further be defined by the bottom layer 170, such that the bottom layer partially forms a boundary of the magnet housing region 150. The magnet housing region 150 is preferably a rectangular prism-shaped void in the microfluidic cartridge 150, and accessible only through one side of the microfluidic cartridge 100, as shown in FIG. 1B. Preferably, the magnet housing region 150 can be reversibly passed over a magnet 152 to house the magnet 152, and retracted to remove the magnet 152 from the magnet housing region 150; however, the magnet 152 may alternatively be irreversibly fixed within the magnet housing region 150 once the magnet 152 enters the magnet housing region 150.”) • U.S. Patent No. 9,403,165 at 12:59-13:2 (“Preferably, the magnet housing region 150 is bounded on at least two sides by the waste chamber 130, and positioned near the middle of the microfluidic cartridge 100, such that a fluidic pathway 165 passing through the magnetic field 156 passes through the magnetic field 156 at least at one point along an intermediate portion of the fluidic pathway 165. Preferably, the magnet housing region 150 also substantially spans at least one dimension of the microfluidic cartridge, such that multiple fluidic pathways 165 of the microfluidic cartridge 100 cross the same magnet housing region 150, magnet 152, and/or magnetic field 156.”) • U.S. Patent No. 9,403,165 at 21:17-32 (“Multiple fluidic pathways may be configured to pass through a single heating region 195 of the microfluidic cartridge 100, a single vent region 190 of the microfluidic cartridge 100, and/or a magnetic field 156 produced by a magnet 152 housed

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		<p>within a single magnet housing region 150. Preferably all fluidic pathways of the set of fluidic pathways 160 are configured to pass through a single heating region 195 of the microfluidic cartridge 100, a single vent region 190 of the microfluidic cartridge 100, and a magnetic field 156 produced by a magnet 152 housed within a single magnet housing region 150; however, alternative embodiments of the set of fluidic pathways 160 of the microfluidic cartridge may comprise different configurations wherein fluidic pathways of the set of fluidic pathways 160 do not share a single heating region 195, a single vent region 190, and/or a magnetic field 156.”)</p> <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 7. The system of claim 1, wherein a retracted configuration of the actuator allows the magnet to retract from the magnet receiving slot. • Claim 8. The system of claim 1, wherein the magnet is configured to provide a magnetic field spanning at least three fluidic pathways configured to facilitate isolation and extraction of three nucleic acid volumes. • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon

Claim	Claim Language	Infringement Evidence
		<p>deformation of the elastomeric layer.</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 7:63-8:6 (“As shown in FIGS. 7A-7C, the cartridge platform 141 is preferably configured to receive a microfluidic cartridge 210 along a cartridge loading guiderail 142 until it reaches a cartridge stop 143, and be vertically displaced by the linear actuator 146, which places a biasing force against the set of springs 148 coupled to the cartridge platform 141. The magnet receiving slot 144 and the set of valve actuation slots 145 provide access, by a magnet 160 and a valve actuation subsystem 170, to the microfluidic cartridge 210, as the microfluidic cartridge is vertically displaced by the linear actuator 146.”) U.S. Patent No. 9,050,594 at FIG. 7A  <p style="text-align: center;">FIG. 7A</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 8:36-49 (“The embodiment of the cartridge platform 141 shown in FIG. 8 also includes a set of valve actuation slots 145, oriented perpendicular to the parallel cartridge loading guiderails 142 and configured to provide access to a valve actuation subsystem 170, and a magnet receiving slot 144 located among the set of valve actuation slots 145. Preferably, the magnet receiving slot 144 and the set of valve actuation slots 145 substantially span a long dimension of the cartridge platform 141, as shown in FIG. 8, and are configured to correspond to locations on a microfluidic cartridge 210 requiring a magnetic field and/or valving to enable processing of a biological sample and nucleic acid detection once the microfluidic cartridge 210 has been aligned within the molecular diagnostic module 130.”) U.S. Patent No. 9,050,594 at 12:64-13:16 (“The magnet 160 of the molecular diagnostic

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		<p>module 130 functions to provide a magnetic field for isolation and extraction of nucleic acids bound to magnetic beads within a microfluidic cartridge 210, aligned within the molecular diagnostic module 130. Preferably, the magnet 160 is fixed within the molecular diagnostic module 130, such that the extended configuration 146 b of the linear actuator 146 allows the magnet 160 to pass through the magnet receiving slot 144 of the cartridge receiving module 140 and into a magnet housing region 218 of the microfluidic cartridge 210. In an example, as shown in FIGS. 7A-7C, the magnet 160 is a rectangular prism-shaped magnet 160 fixed under the cartridge platform 141, and configured to pass through the cartridge platform 141, into a magnet housing region 218 located under the heating region 224 of the microfluidic cartridge 210. Preferably, the magnet 160 is one of two or three magnets lined up in parallel, such that each of the fluidic pathways of a microfluidic cartridge housing the magnets is exposed to two or three times as much magnetic flux, and two to threes [sic] times as many opportunities to capture magnetic beads.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 22:61-23:5 (“The microfluidic cartridge 210 is preferably configured to be received and manipulated by the molecular diagnostic module 130, such that the cartridge receiving module 140 of the molecular diagnostic module 130 receives and aligns the microfluidic cartridge 210 within the molecular diagnostic module 130, the heating and cooling subsystem 150 of the molecular diagnostic module 130 is configured to transfer heat to the heating region 224 of the microfluidic cartridge 210, and the magnet 160 of the molecular diagnostic module 130 is configured to be received by the magnet housing region 218 of the microfluidic cartridge 210 to provide a magnetic field for separation of nucleic acids.”)
1(p)	holding the plurality of magnetic binding particles bound to nucleic acids of the plurality of nucleic acid-containing samples against walls of the plurality of process chambers using the magnetic separator of	<p>The accused workflow comprises holding the plurality of magnetic binding particles bound to nucleic acids of the plurality of nucleic acid-containing samples against walls of the plurality of process chambers using the magnetic separator of the first module.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” <i>Id.</i> at 2:28-2:39.

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	the first module	<ul style="list-style-type: none"> <li data-bbox="615 238 1228 267">• <i>Id.</i> at 2:28 (showing lysate in the s-channel).  <p data-bbox="569 885 884 917">US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> <li data-bbox="615 927 1927 1398">• Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge,

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		<p>in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 5. The method of claim 3, wherein separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture. • Claim 6. The method of claim 5, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety-sample mixture from the process chamber; occluding the fluidic pathway of the cartridge-at a set of occlusion positions upon displacement of pins of the set of pins to generate a path through a magnetic field, and to a waste chamber; and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber. • Claim 10. The method of claim 3, wherein washing the set of moiety-bound nucleic acid particles comprises aspirating the moiety-sample mixture; receiving the cartridge at the cartridge receiving module comprising the set of pins and a cam card interfacing with the set of pins; transitioning the cartridge to an active configuration that disposes the cartridge proximal the set of pins; displacing the first subset of the set of pins in the active configuration of the cartridge, upon translation of the cam card relative to the set of pins, thereby occluding the fluidic pathway of the cartridge at a set of occlusion positions; delivering the moiety-sample mixture into the fluidic pathway, wherein the fluidic pathway is configured to pass through a magnetic field and is coupled to a waste chamber, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field; and delivering a wash solution through the fluidic pathway and into the waste chamber in a continuous flow operation.. • Claim 14. The method of claim 13, further comprising capturing the set of moiety-bound nucleic acid particles within the magnetic field and aspirating the nucleic acid sample from the fluidic pathway. • Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a

Claim	Claim Language	Infringement Evidence
		<p>binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second subset of the set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction.</p> <ul style="list-style-type: none"> • Claim 18. The method of claim 17, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety-sample mixture from the process chamber; occluding the fluidic pathway of the cartridge at a set of occlusion positions upon displacement of the first subset of the set of pins to generate a path through a magnetic field, and to a waste chamber of the cartridge; and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber. • U.S. Patent No. 9,382,532 at 7:31-53 (“In a second variation, the lysed moiety-sample solution can be transferred to a vessel that enables the moiety-bound nucleic acid volume to be captured and the waste volume to be removed in a flow through manner, either against the pores of a filter or in the presence of a magnetic field. In the second variation, the microparticles with bound nucleic acids are retained in a filter zone or a magnetic field zone of the vessel, and the liquid portion is flowed into a "waste chamber". In a specific example of the second variation, a system (such as the one described in U.S. patent application Ser. No. 13/766,359, entitled "System

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		<p>and Method for Processing and Detecting Nucleic Acids") can be used to transfer the lysed moiety-sample solution into a fluidic pathway of a cartridge (such as the one described in U.S. patent application Ser. No. 13/765,996, entitled "Microfluidic Cartridge for Processing and Detecting Nucleic Acids"). In the specific example, the lysed moiety-sample solution can be retained by a magnetic field within a portion of the fluidic pathway upon occlusion of the fluidic pathway at a suitable set of occlusion positions, in order to separate the moiety-bound nucleic acid volume from the waste volume. The waste volume can then be removed by pushing the waste volume to a waste chamber of the cartridge.”)</p> <ul style="list-style-type: none"> • Patent No. 9,382,532 at 8:48-55 (“In the variation of the first example, the microparticles of the moiety-bound nucleic acid volume can be retained by a magnetic field within a portion of the fluidic pathway upon occlusion of the fluidic pathway at a suitable set of occlusion positions, and the wash solution can be delivered through the portion of the fluidic pathway and into a waste chamber of the cartridge to wash the microparticles with the bound target nucleic acid(s).”) • Patent No. 9,382,532 at 11:6-14 (“In a specific example of this variation, a system (such as the one described in U.S. patent application Ser. No. 13/766,359, entitled "System and Method for Processing and Detecting Nucleic Acids") can be used to aspirate the nucleic acid sample from a fluidic path way of a cartridge (such as the one described in U.S. patent application Ser. No. 13/765,996, entitled "Microfluidic Cartridge for Processing and Detecting Nucleic Acids"), while the microparticles are immobilized by a magnet.”) • Patent No. 9,382,532 at 24:57-25:2 (“For example, as shown in FIG. 22B, occluding the fluidic pathway 165 at the first, third, fourth, and sixth occlusion positions 142, 144, 145, 147 forms a truncated pathway by which a volume of a sample fluid, comprising nucleic acids bound to magnetic beads and delivered into the sample port 114, may flow past the second occlusion positions 143 into the capture segment 166 for isolation and purification of nucleic acids using the heating region 195 and the magnetic field 156. Nucleic acids bound to magnetic beads may thus be trapped within the capture segment 166 by the magnetic field 156, while other substances in the volume of sample fluid may pass into the waste chamber 130 by passing the fifth occlusion position 146.”) <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> • Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled

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		<p>to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position of the fluidic pathway, by way of the void of the corrugated surface, the fluidic pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber.</p> <ul style="list-style-type: none"> • Claim 3. The cartridge of claim 1, wherein the waste chamber comprises at least one waste inlet in communication with the opening of the intermediate substrate, and wherein the corrugated surface of the waste chamber further defines a rectangular prismatic void spanning a long dimension of the cartridge that defines a magnet housing region configured to reversibly receive a magnet from the direction perpendicular to a broad face of the first layer, and configured to cross the fluidic pathway. • Claim 4. The cartridge of claim 3, wherein the fluidic pathway comprises a capture segment, downstream of the sample port and configured to cross the magnet housing region multiple times. • Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate. • Claim 15. The cartridge of claim 8, wherein at least one void of the set of voids defined by the corrugated surface of the waste chamber is a rectangular prismatic void spanning a long dimension of the cartridge and defining a magnet housing region configured to cross the first fluidic pathway and the second fluidic pathway.

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		<ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at 14:39-50 (“As shown in FIGS. 1C, 6C, 7 and 9, a fluidic pathway 165 of the set of fluidic pathways 160 is branched and preferably comprises an initial segment 174 fluidically coupled to a fluid channel 119 coupled to a fluid port 118, a sample segment 175 coupled to a sample port 114, a reagent segment 176 coupled to a reagent port 115, a capture segment 166 passing through at least one of the heating region 195 and a magnetic field 156, a vent segment 177 configured to pass through the vent region 190, a segment running to a detection chamber 163, a segment running away from the detection chamber 164, and at least one waste segment 178, 179 configured to transfer a waste fluid to a waste chamber 130.”) U.S. Patent No. 9,403,165 at 16:11-23 (“For example, as shown in FIG. 1D, occluding the fluidic pathway 165 at the first, third, fourth, and sixth occlusion positions 142, 144, 145, 147 forms a truncated pathway by which a volume of a sample fluid, comprising nucleic acids bound to magnetic beads and delivered into the sample port 114, may flow past the second occlusion positions 143 into the capture segment 166 for isolation and purification of nucleic acids using the heating region 195 and the magnetic field 156. Nucleic acids bound to magnetic beads may thus be trapped within the capture segment 166 by the magnetic field 156, while other substances in the volume of sample fluid may pass into the waste chamber 130 by passing the fifth occlusion position 146.”) U.S. Patent No. 9,403,165 at 20:62-21:3 (“The first channel type 171 is preferably used over a majority of a fluidic pathway 165, and preferably in portions near a vent region 190, in a capture segment 166 configured to pass through a magnetic field 156, and in a segment leading to a Detection chamber 163. Preferably, an embodiment of the first channel type 171, comprising a wide channel with little depth is used in regions configured to pass through a magnetic field 156, such that particles in the regions are driven closer to the magnetic field source.”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator

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		<p>allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • Claim 8. The system of claim 1, wherein the magnet is configured to provide a magnetic field spanning at least three fluidic pathways configured to facilitate isolation and extraction of three nucleic acid volumes. • Claim 23. A system for processing and detecting nucleic acids, comprising: a molecular diagnostic module, configured to process a set of biological samples combined with magnetic beads and separate a set of nucleic acid volumes from the set of biological samples combined with magnetic beads, wherein the molecular diagnostic module comprises an actuator configured to displace a cartridge, a set of pins, and at least one cam contacting the set of pins, wherein an extension or retraction of the actuator moves the cartridge, and a displacement of a subset of the set of pins defines a set of pathways in the cartridge, each configured to receive a biological sample combined with magnetic beads of the set of biological samples combined with magnetic beads.
1(q)	moving, using the liquid dispenser, a portion of a solution contained in each of the plurality of process chambers to a waste chamber	<p>The accused workflow comprises moving, using the liquid dispenser, a portion of a solution contained in each of the plurality of process chambers to a waste chamber.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” <i>Id.</i> at 2:28-2:39. • <i>Id.</i> at 2:28 (showing excess solution (light brown) flowing into a self-contained waste chamber).

Claim	Claim Language	Infringement Evidence
		<div data-bbox="659 228 1619 771" data-label="Image"> </div> <ul style="list-style-type: none"> <p>• “A precise volume of air is then applied to remove any remaining liquid into the waste chamber. NeuMoDx wash solution is pumped via the fluid port into the microfluidic cartridge to remove all unbound material, followed by another volume of air to remove excess wash solution. High pH NeuMoDx release reagent is dispensed into the s-channel to cover the beads, and heat is applied to the denaturation process, resulting in released nucleic acid or eluate.” <i>Id.</i> at 2:39-3:12.</p> <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> <p>• Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the</p>

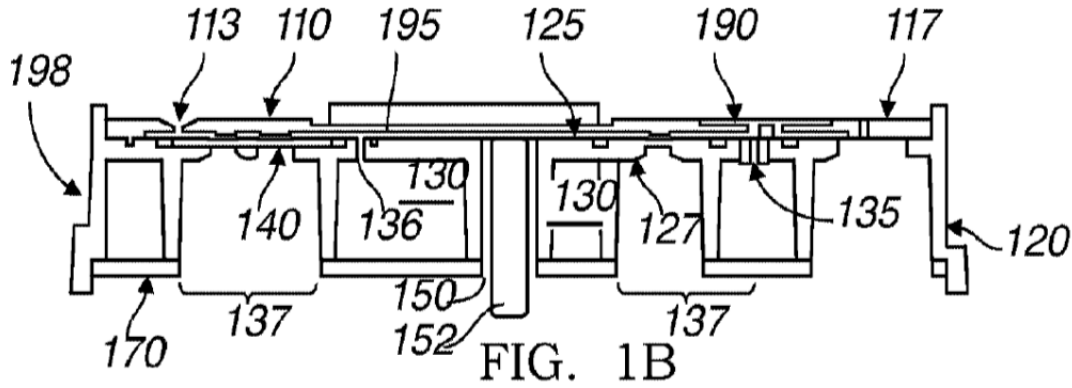
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		<p>cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 6. The method of claim 5, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety-sample mixture from the process chamber; occluding the fluidic pathway of the cartridge-at a set of occlusion positions upon displacement of pins of the set of pins to generate a path through a magnetic field, and to a waste chamber; and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber. • Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20uL of an elution solution characterized by

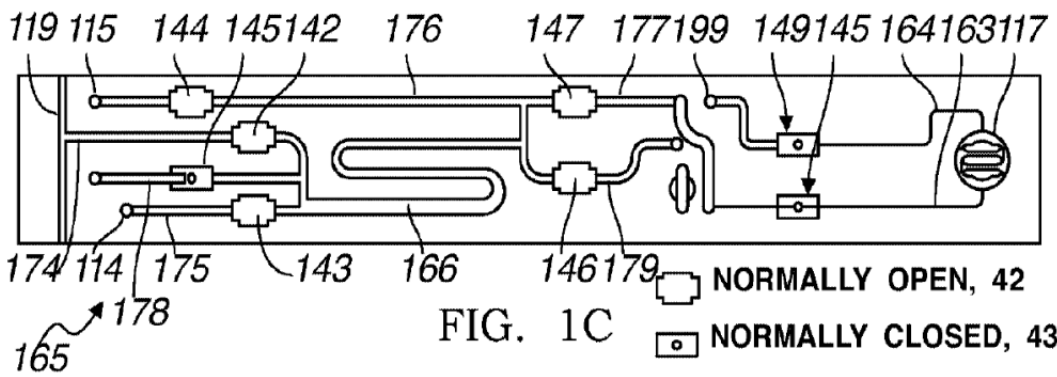
Claim	Claim Language	Infringement Evidence
		<p>a pH greater than 10, in coordination with displacement of a second subset of the set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction.</p> <ul style="list-style-type: none"> • Claim 18. The method of claim 17, wherein magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture comprises aspirating the moiety-sample mixture from the process chamber; occluding the fluidic pathway of the cartridge at a set of occlusion positions upon displacement of the first subset of the set of pins to generate a path through a magnetic field, and to a waste chamber of the cartridge; and delivering the moiety-sample mixture through the path of the fluidic pathway, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field and a waste volume of the moiety-sample mixture is delivered into the waste chamber. • Patent No. 9,382,532 at 6:41-59 (“Step S140 recites separating the moiety-bound nucleic acid volume from the waste volume, and functions to compact or concentrate microparticles coupled to the target nucleic acid(s), by way of the affinity moieties, in order to facilitate removal of the waste volume from the moiety-bound nucleic acid volume. Preferably, the moiety-bound nucleic acid volume is separated using a magnetic-separation method; however the moiety-bound nucleic acid volume can alternatively be separated using methods based upon microparticle size, mass, and/or density (e.g., centrifugation, sedimenting, filtering), and/or focusing methods (e.g., electric field focusing, laser based focusing). Separation in Step S140 can, however, be performed using any other suitable method. In a first variation, wherein the microparticles coupled with affinity moieties have magnetic properties, a magnetic field can be applied to retain the nucleic acid-bound microparticles of the moiety-bound nucleic acid volume, while the waste volume (e.g., cellular debris and other unbound material) is substantially removed by aspiration.”) • U.S. Patent No. 9,382,532 at 7:14-53 (“In Step S140, the lysed moiety-sample solution can be processed within the process chamber to separate the moiety-bound nucleic acid volume from the waste volume; however, the lysed moiety-sample solution can alternatively be transferred to another suitable vessel for separation of the moiety-bound nucleic acid volume from the waste volume. In a first variation, a pipetting system (automatic or manual) can be used to remove the waste volume (e.g., supernatant liquid), and multiple aspirations by the pipetting system may be necessary to ensure as complete a removal of the supernatant as possible. In an example of the first variation, a 1000 micro liter pipette tip can be used to perform gross removal of the waste volume in a first aspiration followed by the use of a finer pipette tip (e.g., 100-200 microliter tip) in additional aspirations, to remove the remainder of the waste

Claim	Claim Language	Infringement Evidence
		<p>volume. In the example, the removal of the waste volume occurs close to the bottom of the process chamber to provide complete liquid removal with minimal bubbling. In a second variation, the lysed moiety-sample solution can be transferred to a vessel that enables the moiety-bound nucleic acid volume to be captured and the waste volume to be removed in a flow through manner, either against the pores of a filter or in the presence of a magnetic field. In the second variation, the microparticles with bound nucleic acids are retained in a filter zone or a magnetic field zone of the vessel, and the liquid portion is flowed into a "waste chamber". In a specific example of the second variation, a system (such as the one described in U.S. patent application Ser. No. 13/766,359, entitled "System and Method for Processing and Detecting Nucleic Acids") can be used to transfer the lysed moiety-sample solution into a fluidic pathway of a cartridge (such as the one described in U.S. patent application Ser. No. 13/765,996, entitled "Microfluidic Cartridge for Processing and Detecting Nucleic Acids"). In the specific example, the lysed moiety-sample solution can be retained by a magnetic field within a portion of the fluidic pathway upon occlusion of the fluidic pathway at a suitable set of occlusion positions, in order to separate the moiety-bound nucleic acid volume from the waste volume. The waste volume can then be removed by pushing the waste volume to a waste chamber of the cartridge.")</p> <ul style="list-style-type: none"> • Patent No. 9,382,532 at 13:42-60 ("A first example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, cerebrospinal fluid (CSF) as a representative biological sample, and Enterovirus (EV) viral particles as the model target. In the first example, 200 μL of CSF was spiked with 2 μL of EV viral particle lysate and then mixed with 500 μL of RNA Collection Buffer 1 (CBR-1) and 300 μL of nuclease-free water in examples of Steps S110 and S120. As a comparison, a similar amount of EV particle lysate was spiked into a 1 mL solution comprised of 500 μL of CBR-1 buffer and 500 μL of nuclease-free water and processed simultaneously. In an example of Step S130, RNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 60 C. Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2\times) with 500 μL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.") <i>See also id.</i> at 14:5-23, 14:41-59, 15:8-24, 15:58-16:12, 16:29-44, 16:61-17:10, 17:27-43, 17:60-18:14, 18:31-47, 19:12-27, 19:46-61, 20:7-23, 20:33-50, 21:23-39, 21:59-22:8, 22:31-49.

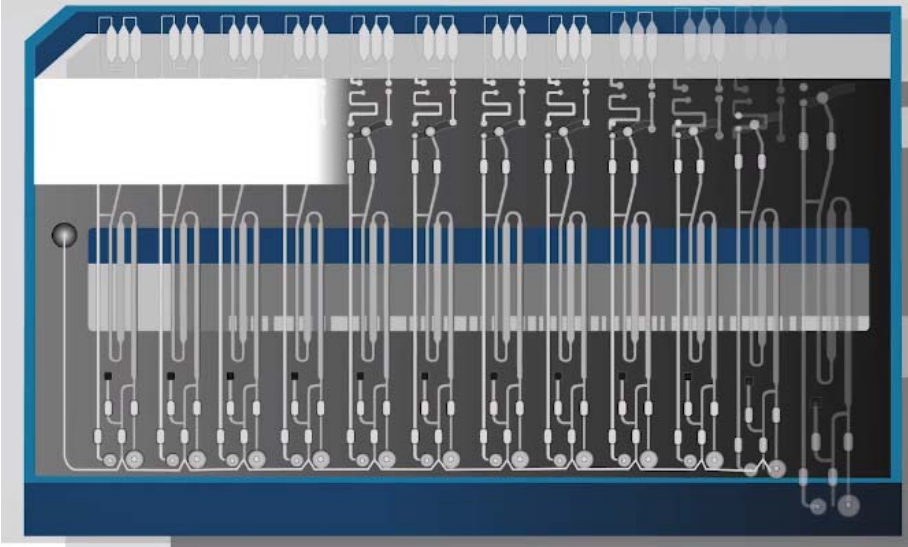
Claim	Claim Language	Infringement Evidence
		<p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> • Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position of the fluidic pathway, by way of the void of the corrugated surface, the fluidic pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber. • Claim 5. The cartridge of claim 4, wherein the fluidic pathway is configured to transfer waste fluid of the sample to the waste chamber through a first waste inlet upstream of the capture segment by way of a first waste segment fluidly coupled to the first waste inlet and an initiating portion of the capture segment, and wherein the fluidic pathway is configured to transfer a second waste fluid to the waste chamber through a second waste inlet downstream of the capture segment by way of a second waste segment fluidly coupled to the second waste inlet and a terminating portion of the capture segment. • Claim 7. The cartridge of claim 6, wherein at least one void of the set of voids defined by the corrugated surface of the waste chamber is defined by five surfaces of the corrugated surface, including a first pair of parallel surfaces and a second pair of parallel surfaces orthogonal to the first pair of parallel surfaces and orthogonal to the broad surface of the first layer, and a surface, coupled to the first pair of surfaces and the second pair of surfaces and proximal to the first layer, having a set of openings for occlusion of the fluidic pathway at the set of occlusion positions, and wherein occluding the fluidic pathway at a first subset of the set of occlusion positions defines a truncated pathway configured to facilitate transfer of waste fluid of the sample to the waste chamber. • Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a

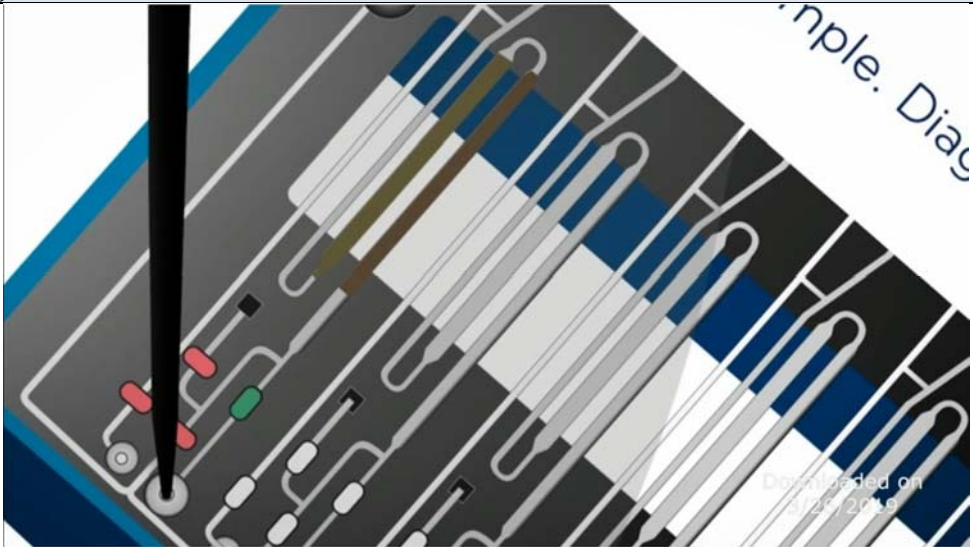
Claim	Claim Language	Infringement Evidence
		<p>film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate.</p> <ul style="list-style-type: none"> • Claim 17. The cartridge of claim 16, wherein the first fluidic pathway is configured to transfer a first waste fluid of the sample to the waste chamber through a first waste inlet, upon occlusion of a first subset of the set of occlusion positions, by way of a first waste segment fluidly coupled to the first waste inlet and a first portion of the first fluidic pathway proximal the first sample port, and wherein the first fluidic pathway is configured to transfer a second waste fluid of the sample to the waste chamber through a second waste inlet, upon occlusion of a second subset of the set of occlusion positions, by way of a second waste segment fluidly coupled to the second waste inlet and a second portion of the first fluidic pathway substantially downstream of the first sample port. • Claim 18. The cartridge of claim 16, wherein the first fluidic pathway is configured to transfer a first waste fluid to the waste chamber through a first waste inlet, upon occlusion of a first subset of the set of occlusion positions, by way of a first waste segment fluidly coupled to the first waste inlet and inline with the first fluidic pathway, and wherein the second fluidic pathway is configured to transfer a second waste fluid to the waste chamber through a second waste inlet, upon occlusion of a second subset of the set of occlusion positions, by way of a second waste segment fluidly coupled to the second waste inlet and inline with the second fluidic pathway. • U.S. Patent No. 9,403,165 at 8:24-32 (“As shown in FIG. 1B, an embodiment of the microfluidic cartridge also comprises an intermediate substrate 120, coupled to the top layer 110 and partially separated from the top layer 110 by a film layer 125, configured to form a waste chamber 130. The intermediate substrate 120 functions to serve as a substrate to which layers of the microfluidic cartridge may be bonded, to provide guides for the valve pins, and to provide a waste chamber volume into which a waste fluid may be deposited.”)


Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at 9:57-10:3 (“As shown in FIG. 1B, the intermediate substrate 120 of an embodiment of the microfluidic cartridge 100 is configured to form a waste chamber 130, which functions to receive and isolate waste fluids generated within the microfluidic cartridge 100. The waste chamber 130 is preferably continuous and accessible by each fluidic pathway 165 of the microfluidic cartridge 100, such that all waste fluids generated within the microfluidic cartridge 100 are deposited into a common waste chamber; however, each fluidic pathway 165 of the microfluidic cartridge 100 may alternatively have its own corresponding waste chamber 130, such that waste fluids generated within a fluidic pathway 165 of the microfluidic cartridge 100 are isolated from waste fluids generated within other fluidic pathways 165 of the microfluidic cartridge 100.”) U.S. Patent No. 9,403,165 at FIG. 1B.  <p style="text-align: center;">FIG. 1B</p> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at 14:39-50 (“As shown in FIGS. 1C, 6C, 7 and 9, a fluidic pathway 165 of the set of fluidic pathways 160 is branched and preferably comprises an initial segment 174 fluidically coupled to a fluid channel 119 coupled to a fluid port 118, a sample segment 175 coupled to a sample port 114, a reagent segment 176 coupled to a reagent port 115, a capture segment 166 passing through at least one of the heating region 195 and a magnetic field 156, a vent segment 177 configured to pass through the vent region 190, a segment running to a detection chamber 163, a segment running away from the detection chamber 164, and at least one waste segment 178, 179 configured to transfer a waste fluid to a waste chamber 130.”) U.S. Patent No. 9,403,165 at FIG. 1C.

Claim	Claim Language	Infringement Evidence
		 <p>FIG. 1C</p> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at 16:19-23 (“Nucleic acids bound to magnetic beads may thus be trapped within the capture segment 166 by the magnetic field 156, while other substances in the volume of sample fluid may pass into the waste chamber 130 by passing the fifth occlusion position 146.”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. Claim 2. The system of claim 1, further comprising a liquid handling system configured to transfer at least one magnetic bead-sample from the capture plate to the molecular diagnostic module, and to aspirate at least one nucleic acid volume from the molecular diagnostic module.

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. U.S. Patent No. 9,050,594 at 30:8-27 (“In a specific example of Step S440, the set of fluidic pathways containing a set of nucleic acid-magnetic bead samples, from the specific example of Step S430, is occluded at a subset of the set of occlusion positions by a valve actuation subsystem of the molecular diagnostic module, to define a set of truncated fluidic pathways coupled to a waste chamber and to a shared fluid port of the microfluidic cartridge for delivery of a wash solution and a release solution. The liquid handling system delivers a wash fluid through the shared fluid port to wash the set of nucleic acid-magnetic bead samples, captured within the magnetic field, and then delivers a release fluid through the shared fluid port to release a set of nucleic acid volumes from the set of nucleic acid-magnetic bead samples. In the specific example, each fluidic pathway is washed sequentially, and the release solution is delivered to each fluidic pathway sequentially to ensure that each lane is provided with substantially equal amounts of wash and release solutions. All waste fluid produced in the specific example of Step S440 pass into the waste chamber coupled to the set of truncated fluidic pathways.”)
1(r)	dispensing, using the liquid dispenser, a wash buffer into the plurality of process chambers	<p>The accused workflow comprises dispensing, using the liquid dispenser, a wash buffer into the plurality of process chambers.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59

Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none"> • “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” <i>Id.</i> at 2:28-2:39. • <i>Id.</i> at 2:28 (showing lysate in the s-channel).

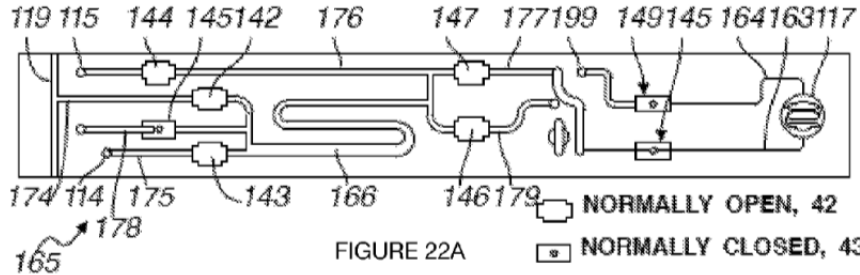
Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none"> • “A precise volume of air is then applied to remove any remaining liquid into the waste chamber. NeuMoDx wash solution is pumped via the fluid port into the microfluidic cartridge to remove all unbound material, followed by another volume of air to remove excess wash solution. High pH NeuMoDx release reagent is dispensed into the s-channel to cover the beads, and heat is applied to the denaturation process, resulting in released nucleic acid or eluate.” <i>Id.</i> at 2:39-3:12. • <i>Id.</i> at 2:43 (showing pumping of the wash solution)

Claim	Claim Language	Infringement Evidence
		 <p>40600100 _Rev-D-IFU-NeuMoDx-WASH-Solution-US-ONLY-FINAL-25Oct2018 (Exhibit 58)</p> <ul style="list-style-type: none"> • “The NeuMoDx™ WASH Solution is a proprietary reagent used for the efficacious extraction of nucleic acids on the NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems (NeuMoDx™ System(s)) in conjunction with other NeuMoDx™ reagents such as the NeuMoDx™ Extraction Plate, NeuMoDx™ lysis buffers, and NeuMoDx™ RELEASE Solution. NeuMoDx WASH Solution is universally used for all tests run on the NeuMoDx Systems.” <i>Id.</i> at 1. • “The NeuMoDx Wash Reagent is a proprietary reagent that removes unbound/non-specifically bound moieties including PCR inhibitors from the magnetic microspheres bound with nucleic acid. It is formulated to work with the proprietary NeuMoDx Extraction Plate reagents to enable the removal of unnecessary material while leaving the desired nucleic acid bound to the magnetic microspheres.” <i>Id.</i> • “The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using

Claim	Claim Language	Infringement Evidence
		<p>the NeuMoDx Wash Reagent and the bound nucleic acid is eluted using NeuMoDx Release Reagent.” <i>Id.</i></p> <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> • Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10. • Claim 10. The method of claim 3, wherein washing the set of moiety-bound nucleic acid particles comprises aspirating the moiety-sample mixture; receiving the cartridge at the cartridge receiving module comprising the set of pins and a cam card interfacing with the set of pins; transitioning the cartridge to an active configuration that disposes the cartridge proximal the set of pins; displacing the first subset of the set of pins in the active configuration of the cartridge, upon translation of the cam card relative to the set of pins, thereby occluding the fluidic pathway of the cartridge at a set of occlusion positions; delivering the moiety-sample mixture into the fluidic pathway, wherein the fluidic pathway is configured to pass through a magnetic field and is coupled to a waste chamber, such that the set of moiety-bound nucleic acid particles is captured within the magnetic field; and delivering a wash solution through the fluidic pathway and into the waste chamber in a

Claim	Claim Language	Infringement Evidence
		<p>continuous flow operation.</p> <ul style="list-style-type: none"> • Claim 11. The method of claim 1, wherein washing the set of moiety-bound nucleic acid particles comprises transferring the moiety-sample mixture to a fluid vessel, capturing the set of moiety-bound nucleic acid particles within the fluid vessel, and washing the set of moiety-bound nucleic acid particles using a series of aspiration and dispensing steps. • Claim 12. The method of claim 11, wherein washing comprises delivering a wash solution through the fluid vessel at a flow rate between 1 and 10 microliters/second, with a total wash solution volume of between 50 and 2000 microliters. • Claim 19. A method for nucleic acid isolation from a biological sample, comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution includes a set of affinity moiety-coated microparticles, comprising a set of microparticles amide-bonded to at least one of Poly(allylamine) of molecular weight <30,000 Da and Polypropylenimine tetramine dendrimer Generation 1; producing a moiety-sample mixture upon combination of the binding moiety solution with the biological sample; producing a set of moiety-bound nucleic acid particles upon incubation of the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of the set of pins includes reversing displacement of at least one pin of the first subset of the set of pins, and reversing occlusion of a portion of the fluidic pathway. • Patent No. 9,382,532 at Abstract (“A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber; mixing the binding moiety solution with a biological sample, within the process chamber, in order to produce a moiety-sample mixture; incubating the moiety-sample mixture during a time window, thereby producing a solution comprising a set of moiety-bound nucleic acid particles and a waste volume; separating the set of moiety-bound nucleic acid particles from the waste volume; washing the set of moiety-bound nucleic acid particles; and releasing a nucleic acid sample from the set of moiety-bound nucleic

Claim	Claim Language	Infringement Evidence
		<p>acid particles. The method preferably utilizes a binding moiety comprising at least one of poly(allylamine) and polypropylenimine tetramine dendrimer, both of which reversibly bind and unbind to nucleic acids based upon environmental pH.”)</p> <ul style="list-style-type: none"> • Patent No. 9,382,532 at 3:4-15 (“As shown in FIGS.1A and 2, a method 100 for nucleic acid isolation comprises receiving a binding moiety solution within a process chamber S110; mixing the binding moiety solution with a biological sample, within the process chamber, in order to produce a moiety-sample solution S120; incubating the moiety-sample solution during a time window S130, thereby producing a lysed solution comprising a moiety-bound nucleic acid volume and a waste volume; separating the moiety-bound nucleic acid volume from the waste volume S140; washing the moiety-bound nucleic acid volume S150; and releasing a nucleic acid sample from the moiety-bound nucleic acid volume S160.”) • Patent No. 9,382,532 at 7:54-8:5 (“Step S150 recites washing the moiety-bound nucleic acid volume, and functions to enable the removal of non-specifically bound moieties and to facilitate a subsequent buffer change in Step S160 by displacing any liquid retained during Step S140. In other steps of the method 100, non-specific binding can occur via electrostatic attraction (e.g., by other negatively charged species), surface adsorption, or any other means; thus, Step S150 can substantially remove a large majority of these non-specifically bound species, especially ones bound to the affinity moieties via means other than electrostatic attraction. Preferably, washing the moiety-bound nucleic acid volume comprises delivering a wash solution to the moiety-bound nucleic acid volume and removing the wash solution and any elements carried in the wash solution; however, washing the moiety-bound nucleic acid volume can alternatively comprise delivering a wash solution through a vessel containing the moiety-bound nucleic acid volume, in order to wash the moiety-bound nucleic acid volume in a flow-through manner. ”) • Patent No. 9,382,532 at 8:48-55 (“In the variation of the first example, the microparticles of the moiety-bound nucleic acid volume can be retained by a magnetic field within a portion of the fluidic pathway upon occlusion of the fluidic pathway at a suitable set of occlusion positions, and the wash solution can be delivered through the portion of the fluidic pathway and into a waste chamber of the cartridge to wash the microparticles with the bound target nucleic acid(s).”) • Patent No. 9,382,532 at 13:42-60 (“A first example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, cerebrospinal fluid (CSF) as a representative biological sample, and Enterovirus (EV) viral particles as the model target. In the

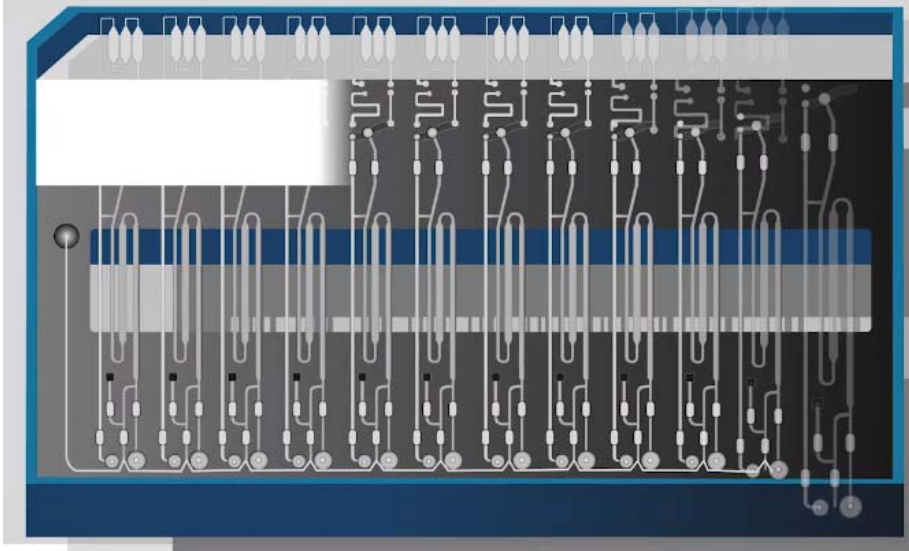
Claim	Claim Language	Infringement Evidence
		<p>first example, 200 μL of CSF was spiked with 2 μL of EV viral particle lysate and then mixed with 500 μL of RNA Collection Buffer 1 (CBR-1) and 300 μL of nuclease-free water in examples of Steps S110 and S120. As a comparison, a similar amount of EV particle lysate was spiked into a 1 mL solution comprised of 500 μL of CBR-1 buffer and 500 μL of nuclease-free water and processed simultaneously. In an example of Step S130, RNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 60 C. Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2\times) with 500 μL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) <i>See also id.</i> at 14:5-23, 14:41-59, 15:8-24, 15:34-55, 15:58-16:12, 16:29-44, 16:61-17:10, 17:27-43, 17:60-18:14, 18:31-47, 19:12-27, 19:46-61, 20:7-23, 20:33-50, 21:23-39, 21:59-22:8, 22:31-49</p> <ul style="list-style-type: none"> Patent No. 9,382,532 at 25:2-16 (“Following this subset of occlusion positions, the occlusion at the first occlusion position 142 may be reversed, as shown in FIG. 22C, and the fluidic pathway 165 may be occluded at the second occlusion position 143 to form a second truncated pathway by which a wash fluid may be delivered through the fluid port 118, into the capture segment 166 (thus washing the trapped magnetic beads), and into the waste chamber 130 by passing the fifth occlusion position 146. The occlusion at the second occlusion position 143 may then be reversed, and the first occlusion position 142 may be occluded (as shown in FIG. 22B), so that other fluidic pathways in the set of fluidic pathways 160 may be washed. After all fluidic pathways have been washed, a volume of air may be transferred through the fluid port 118 to prevent mixture of a wash solution with a release solution.”) U.S. Patent No. 9,382,532 at FIG. 22A:  <p style="text-align: center;">FIGURE 22A</p>

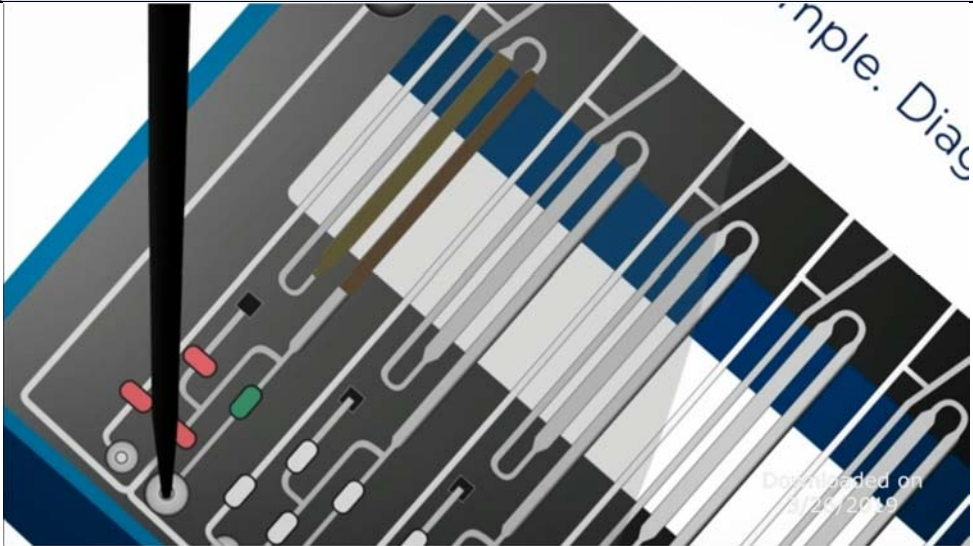
Claim	Claim Language	Infringement Evidence
		<p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> • Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position of the fluidic pathway, by way of the void of the corrugated surface, the fluidic pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber. • U.S. Patent No. 9,403,165 at 4:27-42 (“The fluid port 118 of the top layer 110 of the microfluidic cartridge functions to receive at least one of a wash fluid, a release fluid, and a gas used in a molecular diagnostic procedure, such as PCR. In an embodiment, the wash fluid, the release fluid, and/or the gas are common to all samples being analyzed during a run of the diagnostic procedure using the microfluidic cartridge 100; in this embodiment, as shown in FIG. 1A, the fluid port 118 is preferably a shared fluid port, fluidically coupled to all fluidic pathways 165 coupled to the sample port-reagent port pairs 112, and configured to deliver the same wash fluid, release fluid, and/or gas through the shared fluid port. Alternatively, as shown in FIG. 2, the top layer may comprise more than one fluid port 118, configured to deliver different wash fluids, release fluids, and/or gases to individual or multiple fluidic pathways 165 coupled to the set of sample port-reagent port pairs 112.”) • U.S. Patent No. 9,403,165 at 4:43-62 (“Preferably, the fluid port 118 is located along an edge of the microfluidic cartridge 100, which functions to increase accessibility to the fluid port by a system delivering fluids to the fluid port 118. In a specific embodiment, as shown in FIG. 1A, the fluid port is located approximately midway along an edge of the microfluidic cartridge 100, different from the edge along which the set of sample port-reagent port pairs 112 is located. Alternatively, the fluid port 118 may not be located along an edge of the microfluidic cartridge 100. Additionally, the fluid port 118 is preferably configured to be coupled to a syringe pump for fluid delivery; however, the fluid port 118 may alternatively configured to couple to any


Claim	Claim Language	Infringement Evidence
		<p>appropriate system for fluid delivery. Preferably, the wash fluid is a wash buffer for washing bound nucleic acid samples (i.e. nucleic acids bound to magnetic beads), the release fluid is a reagent for releasing bound nucleic acids samples from the magnetic beads, and the gas is pressurized air for moving fluids and demarcating separate reagents. Alternatively, the wash fluid, release fluid, and gas may be any appropriate liquids or gases used to carry out a molecular diagnostic procedure.”)</p> <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 2. The system of claim 1, further comprising a liquid handling system configured to transfer at least one magnetic bead-sample from the capture plate to the molecular diagnostic module, and to aspirate at least one nucleic acid volume from the molecular diagnostic module. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces

Claim	Claim Language	Infringement Evidence
		<p>a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 3:28-33 (“A heating and cooling subsystem 150, a magnet 160, and a valve actuation subsystem 170 of the molecular diagnostic module 130 then facilitate separation of a set of nucleic acids from the magnetic bead-samples, as the liquid handling system 250 dispenses wash solutions, release solutions, and/or air at appropriate stages.”) • U.S. Patent No. 9,050,594 at 23:41-58 (“The embodiment of the liquid handling system 100 is further configured to facilitate separation of a set of nucleic acids from the magnetic bead-samples, by dispensing a wash solution, a release solution, and/or air into the molecular diagnostic module 130, by the nozzle 149 coupled to the linear actuator 146, at appropriate stages, aspirate the set of nucleic acids from the molecular diagnostic module 130, combine the set of nucleic acids with a set of molecular diagnostic reagents using an assay strip 190, and dispense the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the molecular diagnostic module 130 for further processing and analysis. [Other embodiments of the liquid handling system 250 may be configured to perform alternative molecular diagnostic assay protocols and/or dispense and aspirate alternative fluids into and from other elements supporting a molecular diagnostic protocol.]”) • U.S. Patent No. 9,050,594 at FIG. 14B.

Claim	Claim Language	Infringement Evidence
		<div data-bbox="667 284 1501 844" data-label="Image"> </div> <p data-bbox="667 649 892 698">FIG. 14B</p> <ul style="list-style-type: none"> <li data-bbox="615 868 1921 1409"> <p>U.S. Patent No. 9,050,594 at 25:42-66 (“The syringe pump 265 of the liquid handling system 250 is coupled to a wash solution source 266, a release solution source 267, a source of air 268, and flexible tubing 291, and functions to deliver a wash solution, a release solution, and air through a valve to the molecular diagnostic module 130 to facilitate isolation and purification of nucleic acids from a set of magnetic bead-samples. The flexible tubing 291 is preferably coupled at a first end to the syringe pump, and at a second end to a nozzle 149 coupled to the linear actuator 146 of the molecular diagnostic module 130, as shown in FIG. 14C. As stated earlier, an extended configuration 146 b of the linear actuator 146 is configured to couple the nozzle 149 to a fluid port 222 of a microfluidic cartridge 210 within the molecular diagnostic module 130, such that the wash solution, release solution, and air can be delivered to the microfluidic cartridge 210 at appropriate stages. A specific embodiment of the syringe pump 265 comprises a 4-way valve, is able to pump 20-5000 μL of fluids or air through the 4-way valve at flow rates from 50-500 $\mu\text{L}/\text{min}$, can couple to syringes with between 1 mL and 10 mL capacities, and has a precision of at least 5% with regard to fluid or air delivery. Alternatively, the syringe pump 265 may be any appropriate syringe pump 265 or fluid delivery apparatus</p>

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		<p>configured to deliver a wash solution, a release solution, and air to the molecular diagnostic module 130, as is readily known by those skilled in the art.”)</p>
1(s)	<p>dispensing, using the liquid dispenser, a release buffer into the plurality of process chambers and over the plurality of magnetic binding particles in the plurality of process chambers</p>	<p>The accused workflow comprises dispensing, using the liquid dispenser, a release buffer into the plurality of process chambers and over the plurality of magnetic binding particles in the plurality of process chambers.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59  <ul style="list-style-type: none"> • “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” <i>Id.</i> at 2:28-2:39. • <i>Id.</i> at 2:28 (showing lysate in the s-channel).

Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none"> • “A precise volume of air is then applied to remove any remaining liquid into the waste chamber. NeuMoDx wash solution is pumped via the fluid port into the microfluidic cartridge to remove all unbound material, followed by another volume of air to remove excess wash solution. High pH NeuMoDx release reagent is dispensed into the s-channel to cover the beads, and heat is applied to the denaturation process, resulting in released nucleic acid or eluate.” <i>Id.</i> at 2:39-3:12. • <i>Id.</i> at 2:43-3:00 (showing dispensing of the release solution)

Claim	Claim Language	Infringement Evidence
		 <p>40600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018 (Exhibit 20)</p> <ul style="list-style-type: none"> • “NeuMoDx™ Release Solution is a proprietary reagent that releases captured nucleic acid from NeuMoDx™ proprietary affinity magnetic microspheres providing the eluate at the proper pH for mixing with dried reagents in a NeuMoDx™ test strip and subsequent Real-Time PCR.” <i>Id.</i> at 1. • “The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx™ Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx Wash Reagent and the bound nucleic acid is eluted using NeuMoDx Release Solution.” <i>Id.</i> <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> • Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated

Claim	Claim Language	Infringement Evidence
		<p>microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 13. The method of claim 3, wherein releasing the nucleic acid sample from the set of moiety-bound nucleic acid particles comprises occluding the fluidic pathway of the cartridge, comprising the process chamber, at a set of occlusion positions, upon displacement of pins of the set of pins, to define a path through a magnetic field; delivering the set of moiety-bound nucleic acid particles into the path of the fluidic pathway; and delivering an elution solution into the fluidic pathway, thereby inducing a pH shift configured to release the nucleic acid sample from the set of moiety-bound nucleic acid particles. • Claim 19. A method for nucleic acid isolation from a biological sample, comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution includes a set of affinity moiety-coated microparticles, comprising a set of microparticles amide-bonded to at least one of Poly(allylamine) of molecular weight <30,000 Da and Polypropylenimine tetramine dendrimer Generation 1; producing a moiety-sample mixture upon combination of the binding moiety solution with the biological sample; producing a set of moiety-bound nucleic acid particles upon incubation of the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon

Claim	Claim Language	Infringement Evidence
		<p>displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of the set of pins includes reversing displacement of at least one pin of the first subset of the set of pins, and reversing occlusion of a portion of the fluidic pathway.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,382,532 at 3:31-34 (“The method 100 also preferably enables the release or elution of the desired nucleic acid sample from the microparticle or other surface for further processing and/or characterization.”) • U.S. Patent No. 9,382,532 at 8:56-9:1 (“Step S160 recites releasing a nucleic acid sample from the moiety-bound nucleic acid volume, and functions to separate the microparticles from the bound nucleic acid of the moiety-bound nucleic acid volume by using a reagent (i.e., an elution solution) that mitigates the affinity of the coated microparticles for the target nucleic acid(s) and creates an environment for the release of the target nucleic acid(s) from the microparticles. Preferably, Step S160 enables the elution/release of as much of the bound target nucleic acids in the fastest amount of time; however, Step S160 can alternatively or additionally enable the elution/release of as much of the bound target nucleic acids using the smallest volume of elution solution or any other suitable limiting parameter.”) • U.S. Patent No. 9,382,532 at 9:64-10:13 (“In a specific example of Steps S160 and S161, a system (such as the one described in U.S. patent application Ser. No. 13/766,359, entitled "System and Method for Processing and Detecting Nucleic Acids") can be used to deliver the elution solution into a fluidic pathway of a cartridge (such as the one described in U.S. patent application Ser. No. 13/765,996, entitled "Microfluidic Cartridge for Processing and Detecting Nucleic Acids"). In the variation of the specific example, the microparticles of the moiety-bound nucleic acid volume can be retained by a magnetic field within a portion of the fluidic pathway upon occlusion of the fluidic pathway at a suitable set of occlusion positions, and the elution solution can be delivered through the portion of the fluidic pathway enable release of the nucleic acid sample from the microparticle. Additionally, a heating element of the system can be moved proximal to the portion of the fluidic pathway with the elution solution and the microparticles to further enhance release of the nucleic acid sample.”) • Patent No. 9,382,532 at 13:42-60 (“A first example of the method 100 comprises using PAA

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		<p>affinity moieties coated onto magnetic microparticles, cerebrospinal fluid (CSF) as a representative biological sample, and Enterovirus (EV) viral particles as the model target. In the first example, 200 μL of CSF was spiked with 2 μL of EV viral particle lysate and then mixed with 500 μL of RNA Collection Buffer 1 (CBR-1) and 300 μL of nuclease-free water in examples of Steps S110 and S120. As a comparison, a similar amount of EV particle lysate was spiked into a 1 mL solution comprised of 500 μL of CBR-1 buffer and 500 μL of nuclease-free water and processed simultaneously. In an example of Step S130, RNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 60 C. Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2\times) with 500 μL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) <i>See also id.</i> at 14:5-23, 14:41-59, 15:8-24, 15:34-55, 15:58-16:12, 16:29-44, 16:61-17:10, 17:27-43, 17:60-18:14, 18:31-47, 19:12-27, 19:46-61, 20:7-23, 20:33-50, 21:23-39, 21:59-22:8, 22:31-49.</p> <ul style="list-style-type: none"> • Patent No. 9,382,532 at 25:30-40 (“Thereafter, the occlusion at the fourth occlusion position 145 maybe reversed, creating a fifth truncated pathway, and release solution within the fluidic pathway 165 may be metered by pumping air through the fluid port 118, which functions to push a portion of the release solution into the waste chamber 130. A volume of release solution will still be maintained within the capture segment 166 at this stage. The first and the fourth occlusion positions 142, 145 may then be occluded to form a sixth truncated pathway sealing the volume of release solution, with the captured magnetic beads bound to nucleic acids, within the capture segment 166.”) <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> • Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position

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		<p>of the fluidic pathway, by way of the void of the corrugated surface, the fluidic pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber.</p> <ul style="list-style-type: none"> U.S. Patent No. 9,403,165 at 4:27-42 (“The fluid port 118 of the top layer 110 of the microfluidic cartridge functions to receive at least one of a wash fluid, a release fluid, and a gas used in a molecular diagnostic procedure, such as PCR. In an embodiment, the wash fluid, the release fluid, and/or the gas are common to all samples being analyzed during a run of the diagnostic procedure using the microfluidic cartridge 100; in this embodiment, as shown in FIG. 1A, the fluid port 118 is preferably a shared fluid port, fluidically coupled to all fluidic pathways 165 coupled to the sample port-reagent port pairs 112, and configured to deliver the same wash fluid, release fluid, and/or gas through the shared fluid port. Alternatively, as shown in FIG. 2, the top layer may comprise more than one fluid port 118, configured to deliver different wash fluids, release fluids, and/or gases to individual or multiple fluidic pathways 165 coupled to the set of sample port-reagent port pairs 112.”) U.S. Patent No. 9,403,165 at 16:38-50 (“Thereafter in the first embodiment, as shown in FIG. 1E, the fluidic pathway 165 may be occluded at the second occlusion position 143 and the occlusion at the first occlusion 142 may be reversed, thus creating a third truncated pathway as shown in FIG. 1D. A release solution may then be delivered through the fluid port 118, into the capture segment 166, and to the waste chamber 130 by passing the fifth occlusion position 146. The release solution may then be sealed within a fourth truncated pathway (including the capture segment 166) of the fluidic pathway 165 by occluding the fluidic pathway at the fifth occlusion position 146, as shown in FIG. 1F. A release solution may then be delivered to other fluidic pathways of the set of fluidic pathways 160.”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet

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		<p>to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • Claim 2. The system of claim 1, further comprising a liquid handling system configured to transfer at least one magnetic bead-sample from the capture plate to the molecular diagnostic module, and to aspirate at least one nucleic acid volume from the molecular diagnostic module. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module. • U.S. Patent No. 9,050,594 at 3:28-33 (“A heating and cooling subsystem 150, a magnet 160, and a valve actuation subsystem 170 of the molecular diagnostic module 130 then facilitate separation of a set of nucleic acids from the magnetic bead-samples, as the liquid handling system 250 dispenses wash solutions, release solutions, and/or air at appropriate stages.”) • U.S. Patent No. 9,050,594 at 23:28-53 (“The liquid handling system 250 of the system 100 includes a liquid handling arm 255 and a syringe pump 265, as shown in FIGS. 14A-14C and functions to deliver biological samples, reagents, and gases to elements of the system 100. As described in Section 1, an embodiment of the liquid handling system 250 is configured to aspirate a set of biological samples containing nucleic acids (i.e., impure nucleic acid samples), dispense the set of biological samples into a capture plate no [sic] to be lysed and combined with magnetic

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		<p>beads by a capture plate module 120, aspirate the set of biological samples combined with magnetic beads (i.e., set of magnetic bead-samples) from the capture plate 110, and dispense the set of magnetic bead-samples into microfluidic cartridge 210 located in a molecular diagnostic module 130. The embodiment of the liquid handling system 100 is further configured to facilitate separation of a set of nucleic acids from the magnetic bead-samples, by dispensing a wash solution, a release solution, and/or air into the molecular diagnostic module 130, by the nozzle 149 coupled to the linear actuator 146, at appropriate stages, aspirate the set of nucleic acids from the molecular diagnostic module 130, combine the set of nucleic acids with a set of molecular diagnostic reagents using an assay strip 190, and dispense the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the molecular diagnostic module 130 for further processing and analysis.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at FIG. 14B. <div data-bbox="667 727 1501 1284"> <p>FIG. 14B</p> </div> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 25:42-57 (“The syringe pump 265 of the liquid handling system 250 is coupled to a wash solution source 266, a release solution source 267, a source of air 268, and flexible tubing 291, and functions to deliver a wash solution, a release solution, and

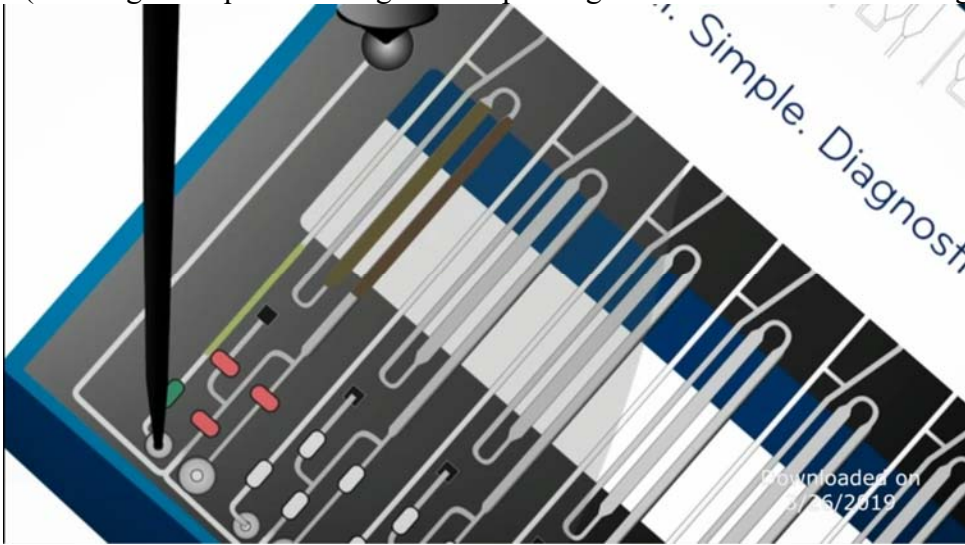
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		<p>air through a valve to the molecular diagnostic module 130 to facilitate isolation and purification of nucleic acids from a set of magnetic bead-samples. The flexible tubing 291 is preferably coupled at a first end to the syringe pump, and at a second end to a nozzle 149 coupled to the linear actuator 146 of the molecular diagnostic module 130, as shown in FIG. 14C. As stated earlier, an extended configuration 146 b of the linear actuator 146 is configured to couple the nozzle 149 to a fluid port 222 of a microfluidic cartridge 210 within the molecular diagnostic module 130, such that the wash solution, release solution, and air can be delivered to the microfluidic cartridge 210 at appropriate stages.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 29:57-30:7 (“Preferably, Step S443 comprises defining at least one truncated fluidic pathway coupled to a waste chamber and to a fluid port, which functions to facilitate washing of at least one nucleic acid-magnetic bead sample in the set of nucleic acid-magnetic bead samples, and releasing of at least one nucleic acid volume from the set of nucleic acid-magnetic bead samples. Step S440 may additionally comprise delivering a wash solution through a portion of at least one fluidic pathway S444, such as the truncated fluidic pathway defined in Step S443, and delivering a release solution through a portion of at least one fluidic pathway S445, such as the truncated fluidic pathway defined in Step S443. Step S444 functions to wash at least one nucleic acid-magnetic bead sample in the set of nucleic acid-magnetic bead samples, and Step S445 functions to release at least one nucleic acid volume from the set of nucleic acid-magnetic bead samples. The heater provided in Step S442 may be activated after Step S445 to induce a pH shift.”)
1(t)	heating the release buffer in the plurality of process chambers to between about 50°C and about 85°C using the heater assembly of the first module	<p>The accused workflow comprises heating the release buffer in the plurality of process chambers to between about 50°C and about 85°C using the heater assembly of the first module.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “Once the crude lysate is dispensed, a series of valves directs the flow to the s-channel, where the paramagnetic beads are captured utilizing an independent magnet for each channel, with the excess solution flowing into a self-contained waste chamber.” <i>Id.</i> at 2:28-2:39. • <i>Id.</i> at 2:28 (showing lysate in the s-channel).

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		<div data-bbox="659 228 1619 769" data-label="Image"> </div> <ul style="list-style-type: none"> • “A precise volume of air is then applied to remove any remaining liquid into the waste chamber. NeuMoDx wash solution is pumped via the fluid port into the microfluidic cartridge to remove all unbound material, followed by another volume of air to remove excess wash solution. High pH NeuMoDx release reagent is dispensed into the s-channel to cover the beads, and heat is applied to the denaturation process, resulting in released nucleic acid or eluate.” <i>Id.</i> at 2:39-3:12. <p>On information and belief, the accused system comprises heating the release buffer in the plurality of process chambers to between about 50°C and about 85°C using the heater assembly of the first module.</p> <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> • Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity

Claim	Claim Language	Infringement Evidence
		<p>moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 17. A method for total nucleic acid extraction, comprising simultaneous isolation and concentration of DNA and RNA from a biological sample, the method comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of magnetic microparticles; mixing the binding moiety solution with between 10uL and 2mL of a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material, comprising target DNA and RNA, of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; magnetically separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; and eluting a nucleic acid sample comprising target DNA and RNA from the set of moiety-bound nucleic acid particles, into less than 20uL of an elution solution characterized by a pH greater than 10, in coordination with displacement of a second subset of the set of pins to modulate flow in the fluidic pathway, thereby facilitating total nucleic acid extraction. • Claim 19. A method for nucleic acid isolation from a biological sample, comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution includes a set of affinity moiety-coated microparticles, comprising a set of microparticles amide-bonded to at

Claim	Claim Language	Infringement Evidence
		<p>least one of Poly(allylamine) of molecular weight <30,000 Da and Polypropylenimine tetramine dendrimer Generation 1; producing a moiety-sample mixture upon combination of the binding moiety solution with the biological sample; producing a set of moiety-bound nucleic acid particles upon incubation of the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution, in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of the set of pins includes reversing displacement of at least one pin of the first subset of the set of pins, and reversing occlusion of a portion of the fluidic pathway.</p> <ul style="list-style-type: none"> • Patent No. 9,382,532 at 9:31-62 (“In some variations, Step S160 can further comprise Step S161, which recites heating the moiety-bound nucleic acid volume. Step S161 functions to provide additional environmental conditions that facilitate release of the nucleic acid sample from the microparticles, and can further function to mitigate effects of proteolytic enzymes that are used in Steps S110, S120, and/or S130 or that may be released from the biological sample containing the nucleic acid. Preferably, an elevated temperature in combination with an elevated pH resulting from the elution solution provides the enhanced conditions to facilitate the release of the nucleic acid sample. Furthermore, an elevated temperature (e.g., elevating a sample eluted at room temperature to 85 C) can function to minimize protease enzyme activity in the eluted nucleic acid and thereby improve the robustness of the detection of the target nucleic acid sample during processing in variations of Step S110; however, the method 100 can alternatively omit Step S161 in applications wherein heating the moiety-bound nucleic acid volume is undesirable and/or unnecessary. Furthermore, variations of Step S161 can comprise heating at higher temperatures for shorter time periods, or heating at lower temperatures for longer time periods. In an example of Step S161, heating comprises elevating the temperature of the moiety-bound nucleic acid volume to 80-85 C, for 3 minutes, and in another example, heating comprises elevating the temperature of the moiety-bound nucleic acid volume to 50-70 C, for 3-10 minutes. In other examples, the elevation temperature can be maintained at a desired set-point for

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		<p>as low as 1 minute or as high as 30 minutes. Further, elution conditions may be optimized to ensure that the bound nucleic acid is only eluted in the presence of the high pH solution at the elevated temperature for a specified amount of time.”)</p> <ul style="list-style-type: none"> • Patent No. 9,382,532 at 10:46-57 (“In specific examples, however, Step S165 can comprise any combination of: not washing the moiety-bound nucleic acid volume, passively washing the moiety-bound nucleic acid volume, not removing a wash solution from the moiety-bound nucleic acid volume, washing the moiety-bound nucleic acid volume with a Tris solution (e.g., 1 mM Tris solution), eluting the nucleic acid sample at room temperature, eluting the nucleic acid sample at 99 C, eluting the nucleic acid sample at 55 C, and not resuspending moiety-bound microparticles in a release buffer, any combination of which can affect amplification of the nucleic acids or the process control.”) • Patent No. 9,382,532 at 13:42-60 (“A first example of the method 100 comprises using PAA affinity moieties coated onto magnetic microparticles, cerebrospinal fluid (CSF) as a representative biological sample, and Enterovirus (EV) viral particles as the model target. In the first example, 200 µL of CSF was spiked with 2 uL of EV viral particle lysate and then mixed with 500 µL of RNA Collection Buffer 1 (CBR-1) and 300 µL of nuclease-free water in examples of Steps S110 and S120. As a comparison, a similar amount of EV particle lysate was spiked into a 1 mL solution comprised of 500 µL of CBR-1 buffer and 500 µL of nuclease-free water and processed simultaneously. In an example of Step S130, RNA was allowed to bind to the PAA affinity moieties coated onto magnetic microparticles for 10 minutes at 60 C. Upon removal of the unbound supernatant in an example of Step S140, the magnetic microparticles with bound RNA were washed twice (2×) with 500 µL of WSH-1 solution in an example of Step S150 and the captured RNA was eluted from the affinity matrix by using ELU-2 at 85 C for 3 minutes in an example of Step S160.”) <i>See also id.</i> at 14:5-23, 14:41-59, 15:8-24, 15:34-55, 15:58-16:12, 16:29-44, 16:61-17:10, 17:27-43, 17:60-18:14, 18:31-47, 19:12-27, 19:46-61, 20:7-23, 20:33-50, 21:23-39, 21:59-22:8, 22:31-49.
1(u)	using the liquid dispenser, withdrawing liquid containing	The accused workflow comprises using the liquid dispenser, withdrawing liquid containing extracted nucleic acids from the plurality of process chambers.

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	extracted nucleic acids from the plurality of process chambers; and	<p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “Liquid Handling Processing C: The Test Strip. After piercing the test strip, the liquid handling robot moves to the PCR port or p-port of the microfluidic cartridge, where it aspirates the eluate out of the cartridge into the pipette tip. Once the aspiration step is complete, the eluate is delivered to the appropriate wells in the NeuMoDx test strip, where it is dispensed and aspirated ten times to ensure homogeneous resuspension of the NeuDry PCR reagents. The sample mixes with primers and probes.” <i>Id.</i> at 3:12-3:57. • <i>Id.</i> at 3:57 (showing the liquid handling robot aspirating the eluate out of the cartridge at the p-  <p>port).</p> <p><i>NeuMoDx Molecular N288 System</i>, http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ TECHNOLOGY” hyperlink at https://player.vimeo.com/video/281470603. (Exhibit 17)</p> <ul style="list-style-type: none"> • At 4:17 (showing the liquid dispenser at the microfluidic cartridge)

Claim	Claim Language	Infringement Evidence
		 <p>US9382532 (Exhibit 52)</p> <ul style="list-style-type: none"> Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge,

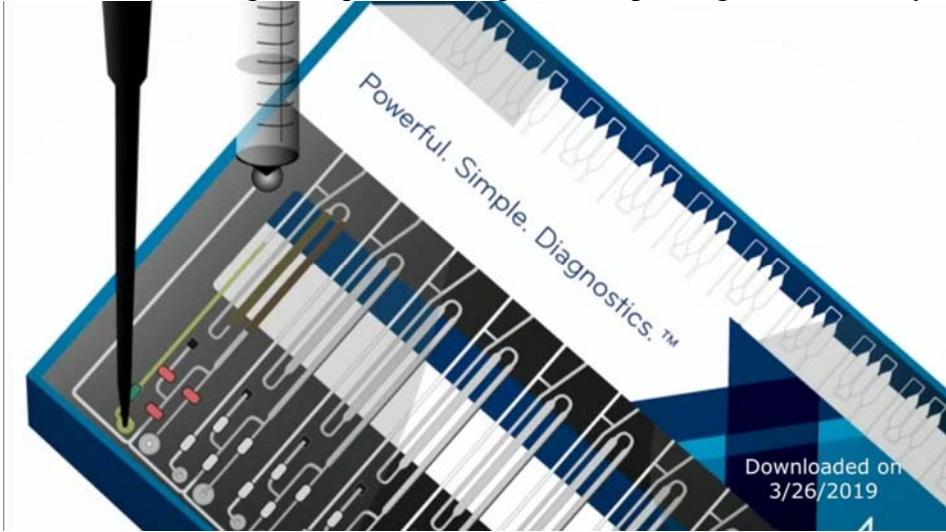
Claim	Claim Language	Infringement Evidence
		<p>in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 14. The method of claim 13, further comprising capturing the set of moiety-bound nucleic acid particles within the magnetic field and aspirating the nucleic acid sample from the fluidic pathway. • Patent No. 9,382,532 at 25:51-58 (“Thereafter in the first illustration, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100.”) <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> • Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position of the fluidic pathway, by way of the void of the corrugated surface, the fluidic pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber. • Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and


Claim	Claim Language	Infringement Evidence
		<p>formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,403,165 at 17:6-13 (“Thereafter in the first embodiment, as shown in FIG. H the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 micro liters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100.”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 2. The system of claim 1, further comprising a liquid handling system configured to transfer at least one magnetic bead-sample from the capture plate to the molecular diagnostic module, and to aspirate at least one nucleic acid volume from the molecular diagnostic module. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume


Claim	Claim Language	Infringement Evidence
		<p>to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 23. A system for processing and detecting nucleic acids, comprising: a molecular diagnostic module, configured to process a set of biological samples combined with magnetic beads and separate a set of nucleic acid volumes from the set of biological samples combined with magnetic beads, wherein the molecular diagnostic module comprises an actuator configured to displace a cartridge, a set of pins, and at least one cam contacting the set of pins, wherein an extension or retraction of the actuator moves the cartridge, and a displacement of a subset of the set of pins defines a set of pathways in the cartridge, each configured to receive a biological sample combined with magnetic beads of the set of biological samples combined with magnetic beads. • Claim 24. The system of claim 23, further comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample, a lysing reagent, and a sample process control, wherein the capture plate facilitates production of at least one biological sample combined with magnetic beads; an assay strip comprising at least one reagent well containing a molecular diagnostic reagent volume configured to be combined with a nucleic acid volume of the set of nucleic acid volumes to produce at least one nucleic acid-reagent mixture; and a liquid handling system configured to transfer at least one biological sample combined with magnetic beads from the capture plate to the molecular diagnostic module, transfer at least one nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer at least one nucleic acid-reagent mixture from the assay strip back to the molecular diagnostic module. • U.S. Patent No. 9,050,594 at 3:28-41 (“A heating and cooling subsystem 150, a magnet 160, and a valve actuation subsystem 170 of the molecular diagnostic module 130 then facilitate separation of a set of nucleic acids from the magnetic bead-samples, as the liquid handling system 250

Claim	Claim Language	Infringement Evidence
		<p>dispenses wash solutions, release solutions, and/or air at appropriate stages. The liquid handling system 250 then aspirates the set of nucleic acids from the microfluidic cartridge 210 contained within the molecular diagnostic module 130, combines the set of nucleic acids with a set of molecular diagnostic reagents using an assay strip 190, and dispenses the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the microfluidic cartridge 210 within the molecular diagnostic module 130.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 23:41-53 (“The embodiment of the liquid handling system 100 is further configured to facilitate separation of a set of nucleic acids from the magnetic bead-samples, by dispensing a wash solution, a release solution, and/or air into the molecular diagnostic module 130, by the nozzle 149 coupled to the linear actuator 146, at appropriate stages, aspirate the set of nucleic acids from the molecular diagnostic module 130, combine the set of nucleic acids with a set of molecular diagnostic reagents using an assay strip 190, and dispense the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the molecular diagnostic module 130 for further processing and analysis.”) • U.S. Patent No. 9,050,594 at FIG. 14B. <div data-bbox="667 836 1501 1396"> <p>FIG. 14B</p> </div>

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 30:28-37 (“Step S450 recites combining each nucleic acid volume of the set of nucleic acid volumes with a molecular diagnostic reagent of a set of molecular diagnostic reagents to produce a set of nucleic acid-reagent mixtures, which functions to prepare the set of nucleic acid volumes to be detected. For each nucleic acid volume in the set of nucleic acid volumes, Step S450 preferably comprises aspirating an entire volume of the nucleic acid volume from its corresponding fluidic pathway, and transferring the nucleic acid volume to a well containing a molecular diagnostic reagent.”) U.S. Patent No. 9,050,594 at 30:54-61 (“In a first variation of Step S450 as shown in FIG. 16A, a nucleic acid volume is aspirated and combined with a molecular diagnostic reagent for a single assay. In the first variation of Step S450, a set of nucleic acid volumes may thus be aspirated simultaneously, and each nucleic acid volume may be transferred to an individual well to be combined with a molecular diagnostic reagent of a set of molecular diagnostic reagents to produce a set of nucleic acid-reagent mixtures.”)
1(v)	dispensing the nucleic acid extracted from the plurality of nucleic-acid containing samples into the second module.	<p>The accused workflow comprises dispensing the nucleic acid extracted from the plurality of nucleic-acid containing samples into the second module.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “Liquid Handling Processing C: The Test Strip. After piercing the test strip, the liquid handling robot moves to the PCR port or p-port of the microfluidic cartridge, where it aspirates the eluate out of the cartridge into the pipette tip. Once the aspiration step is complete, the eluate is delivered to the appropriate wells in the NeuMoDx test strip, where it is dispensed and aspirated ten times to ensure homogeneous resuspension of the NeuDry PCR reagents. The sample mixes with primers and probes.” <i>Id.</i> at 3:12-3:57. “The liquid handling robot aspirates the PCR-ready solution and transfers it back to the cartridge where it dispenses into the same p-port from which the sample was aspirated. A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins. During a series of independent heat on-heat off sequences, an optical scanner measures the level of fluorescence emitted, and converts it into the qualitative or quantitative results which are displayed as amplification curves for analysis by

Claim	Claim Language	Infringement Evidence
		<p>the laboratorian.” <i>Id.</i> at 3:57-4:26.</p> <ul style="list-style-type: none"> • <i>Id.</i> at 3:57 (showing the liquid handling robot dispensing the PCR-ready solution at the p-port).  <p><i>NeuMoDx Molecular N288 System</i>, http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ TECHNOLOGY” hyperlink at https://player.vimeo.com/video/281470603. (Exhibit 17)</p> <ul style="list-style-type: none"> • At 4:17 (showing the liquid dispenser at the microfluidic cartridge)

Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none">• At 4:29 (showing the liquid dispenser at the reagent strip)

Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none">• At 4:36 (showing the liquid dispenser returning to the microfluidic cartridge)

Claim	Claim Language	Infringement Evidence
		 <p data-bbox="567 898 884 930">US9382532 (Exhibit 52)</p> <ul data-bbox="615 938 1927 1409" style="list-style-type: none"> • Claim 1. A method for nucleic acid isolation comprising: receiving a binding moiety solution within a process chamber, wherein the binding moiety solution comprises a collection buffer and a set of affinity moiety-coated microparticles, wherein the set of affinity moiety-coated microparticles comprises Polypropylenimine tetramine dendrimer Generation 1 amide-bonded to a set of microparticles; contacting the binding moiety solution with a biological sample, within the process chamber, thereby producing a moiety-sample mixture; incubating the moiety-sample mixture to reversibly bind nucleic acid material of the biological sample to the set of affinity moiety-coated microparticles, thereby producing a set of moiety-bound nucleic acid particles; receiving a cartridge at a cartridge receiving module comprising a set of pins, each pin in the set of pins displaceable between a first position and a second position; occluding a fluidic pathway of the cartridge upon displacement of a first subset of the set of pins; separating the set of moiety-bound nucleic acid particles from the moiety-sample mixture, within the fluidic pathway of the cartridge; washing the set of moiety-bound nucleic acid particles within the fluidic pathway of the cartridge,

Claim	Claim Language	Infringement Evidence
		<p>in coordination with displacement of a second subset of the set of pins, wherein displacement of the second subset of pins includes reversal of displacement of at least one pin in the first subset of the set of pins, in reversing occlusion of a portion of the fluidic pathway; and releasing a nucleic acid sample from the set of moiety-bound nucleic acid particles with an elution solution characterized by a pH greater than 10.</p> <ul style="list-style-type: none"> • Claim 16. The method of claim 1, further comprising processing the nucleic acid sample, wherein processing the nucleic acid sample comprises modulating the fluidic pathway of the cartridge upon displacement of a third subset of the set of pins, thereby defining a path to a diagnostic chamber of the cartridge, delivering the nucleic acid sample to the diagnostic chamber, and amplifying nucleic acids of the nucleic acid sample within the diagnostic chamber by polymerase chain reaction. • U.S. Patent No. 9,382,532 at 11:2-23 (“In one variation, the nucleic acid sample eluted from the microparticles can be aspirated (e.g., by a pipette tip or by a fluid handling system) into another process chamber and combined with process reagents for further processing and characterization. In a specific example of this variation, a system (such as the one described in U.S. patent application Ser. No. 13/766,359, entitled "System and Method for Processing and Detecting Nucleic Acids") can be used to aspirate the nucleic acid sample from a fluidic pathway of a cartridge (such as the one described in U.S. patent application Ser. No. 13/765,996, entitled "Microfluidic Cartridge for Processing and Detecting Nucleic Acids"), while the microparticles are immobilized by a magnet. The system can then combine the nucleic acid sample with process reagents (e.g., PCR reagents) in a separate container (e.g., assay plate), and then transfer the nucleic acid sample combined with process reagents to a detection chamber of the fluidic pathway (upon occlusion and/or opening of the fluidic channel at another subset of occlusion positions). The nucleic acid sample combined with process reagents can then be processed within a diagnostic chamber that is coupled to the fluidic pathway.”) • Patent No. 9,382,532 at 25:61-67 (“Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position (normally closed) open.”) <p>US9403165 (Exhibit 27)</p>

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • Claim 1. A cartridge for processing a sample, the cartridge comprising: a first layer comprising a sample port and a fluid port at a broad surface of the first layer; an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, and configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a void external to the waste chamber; and a fluidic pathway, superior to the intermediate substrate and at least partially separated from the corrugated surface of the waste chamber by an elastomeric layer, wherein the fluidic pathway is fluidly coupled to the sample port and the fluid port, and wherein, upon deformation of the elastomeric layer at an occlusion position of the fluidic pathway, by way of the void of the corrugated surface, the fluidic pathway is configured to transfer waste fluid through an opening of the intermediate substrate and into an interior portion of the corrugated surface of the waste chamber. • Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate. • U.S. Patent No. 9,403,165 at 17:17-23 (“Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position (normally closed) open.”) <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume

Claim	Claim Language	Infringement Evidence
		<p>to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 23. A system for processing and detecting nucleic acids, comprising: a molecular diagnostic module, configured to process a set of biological samples combined with magnetic beads and separate a set of nucleic acid volumes from the set of biological samples combined with magnetic beads, wherein the molecular diagnostic module comprises an actuator configured to displace a cartridge, a set of pins, and at least one cam contacting the set of pins, wherein an extension or retraction of the actuator moves the cartridge, and a displacement of a subset of the set of pins defines a set of pathways in the cartridge, each configured to receive a biological sample combined with magnetic beads of the set of biological samples combined with magnetic beads. • Claim 24. The system of claim 23, further comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample, a lysing reagent, and a sample process control, wherein the capture plate facilitates production of at least one biological sample combined with magnetic beads; an assay strip comprising at least one reagent well containing a molecular diagnostic reagent volume configured to be combined with a nucleic acid volume of the set of nucleic acid volumes to produce at least one nucleic acid-reagent mixture; and a liquid handling system configured to transfer at least one biological sample combined with magnetic beads from the capture plate to the molecular diagnostic module, transfer at least one nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer at least one nucleic acid-reagent mixture from the assay strip back to the molecular diagnostic module. • U.S. Patent No. 9,050,594 at 3:20-46 (“The liquid handling system 250 then aspirates the set of nucleic acids from the microfluidic cartridge 210 contained within the molecular diagnostic

Claim	Claim Language	Infringement Evidence
		<p>module 130, combines the set of nucleic acids with a set of molecular diagnostic reagents using an assay strip 190, and dispenses the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the microfluidic cartridge 210 within the molecular diagnostic module 130. The detection chamber heaters 157, optical subsystem 180 and valve actuation subsystem 170 of the molecular diagnostic module 130 then facilitate analysis of the set of nucleic acid-reagent mixtures by a processor configured to display information on a user interface.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 23:41-53 (“The embodiment of the liquid handling system 100 is further configured to facilitate separation of a set of nucleic acids from the magnetic bead-samples, by dispensing a wash solution, a release solution, and/or air into the molecular diagnostic module 130, by the nozzle 149 coupled to the linear actuator 146, at appropriate stages, aspirate the set of nucleic acids from the molecular diagnostic module 130, combine the set of nucleic acids with a set of molecular diagnostic reagents using an assay strip 190, and dispense the set of nucleic acids combined with the set of molecular diagnostic reagents (i.e., set of nucleic acid-reagent mixtures) into the molecular diagnostic module 130 for further processing and analysis..”) • U.S. Patent No. 9,050,594 at FIG. 14B.

Claim	Claim Language	Infringement Evidence
		<div data-bbox="661 287 1501 846" data-label="Image"> <p>FIG. 14B</p> </div> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 31:32-37 (“Step S460 recites transferring each of the set of nucleic acid-reagent mixtures, through the corresponding fluidic pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers, which functions to deliver the set of nucleic acid-reagent mixtures to an isolated detection chamber for further processing and analysis.”)

EXHIBIT 93



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SECTION 1: Identification

- 1.1 Product Name** NeuMoDx™ Extraction Plate
Product Code 100200
- 1.2. Relevant identified use** For *In Vitro* Diagnostic Use
- 1.3 Manufacturer** **NeuMoDx Molecular Inc.**
 1250 Eisenhower Pl
 Ann Arbor, MI 48108, USA
www.neumodx.com
info@neumodx.com
- Telephone (General)** 1-844-527-0111
- 1.4 Distributor** **QIAGEN GmbH**
QIAGEN Str. 1,
40724 Hilden
Germany
Technical Support call 00800-22-44-6000
www.qiagen.com/Support
- 1.5 EMERGENCY TELEPHONE NUMBER:**
US 24-HR Emergency Exposure 1-800-222-1222
 American Association of Poison Control Centers
- Outside USA** **Technical Support** call 00800-22-44-6000

SECTION 2: Hazards identification

EU/EEC

According to: (1) Regulation (EC) No 1272/2008 (CLP)/REACH 1907/2006 [amended by 453/2010]
 and (2) US Regulation 29 CFR 1910 (OSHA HCS)

- 2.1. Classification of the substance or mixture**
 Respiratory Sensitization (Category 1)
 Skin Corrosion/Irritation (Category 3)

2.2 Label elements

GHS Label Elements: The product is labelled according to the Globally Harmonized System (GHS).



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Hazard pictograms



GHS08

Signal word: DANGER

Hazard-Determining components of labeling:

Proteinase K

Hazard Statements:

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled
 H316 Causes mild skin irritation.

Precautionary statements:

P261 Avoid breathing dust/fume/gase/mist/vapors/spray
 P342+P311 If experiencing respiratory symptoms: Call a Poison Center or doctor/physician
 P332+313 If skin irritation occurs, get medical advice/attention.
 P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing

Other Hazards

Hazards not otherwise classified (HNOC) or not covered by GHS – none

2.3 Other Information

All other reagents within this buffer are not considered hazardous under US hazard communication regulations (29 CFR 1910.1200), EU directives for classification and labeling of substances or mixtures or the Global Harmonization System for classification and labeling of substances or mixtures.

SECTION 3: Composition/information on Hazardous Ingredients

3.1 Substances

Material does not meet the criteria of a substance.

3.2 Mixtures

Chemical Characterization:

Mixture of chemical and/or biological substances for *in vitro* diagnostic use

Hazardous chemical ingredients per U.S. OSHA criteria (29 CFR 1910.1200 Hazard Communication):

Name	Identifiers	Weight %	GHS-US classification
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Proteinase K	CAS 39450-01-6	5-9%	Respiratory Sensitization, 1 Skin Corrosion/Irritation, 3
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SECTION 4: First aid measures

4.1 Description of first aid measures:

Immediate medical attention needed:

No.

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

After Inhalation

First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. Move exposed personnel to fresh air. Administer oxygen if breathing is difficult. Keep patient warm. Consult doctor if symptoms persist.

After skin contact

First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. Take off any clothing that the product touched. Rinse skin with running water for 15 to 20 minutes. Seek medical attention if irritation or signs of toxicity occur.

After eye contact

First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. In case of contact with substance, immediately flush eyes with running water for at least 20 minutes. If eye irritation persists, seek medical attention.

After swallowing

First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. Rinse mouth with water. If irritation or signs of toxicity occur, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Causes respiratory irritation and mild skin irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Notes for the doctor: All treatments should be based on observed signs and symptoms of distress in the patient. Consideration should be given to the possibility that overexposure to materials other than this product may have occurred.

SECTION 5: Firefighting measures



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5.1 Extinguishing media

Suitable extinguishing media:

Use alcohol resistant foam, carbon dioxide, water, or dry chemical spray. Use water spray to cool fire-exposed containers.

Unsuitable extinguishing media:

Unknown.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products:

The product is non-reactive under normal conditions of use, storage, and transport.

5.3 Advice for fire-fighters

As in any fire, wear self-contained breathing apparatus pressure demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment, and emergency procedures

If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8).

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Take steps to avoid release into the environment.

6.3 Methods and material for containment and clean-up

Contain spill and collect, as appropriate. Transfer to a chemical waste container or soak up with inert absorbent material and dispose of in accordance with local regulations.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Ensure good ventilation in the workplace. Avoid contact with skin and eyes. Avoid formation of aerosols. Wear personal protective equipment. Wash contaminated clothing before reuse. Do not eat, drink, or smoke when using this product. Always wash hands after handling the product.

7.2 Precautions for storage

Keep in a dry place and store at room temperature.

SECTION 8: Exposure controls/personal protection



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8.1 Occupational Exposure Limits

Chemical/Biological name	Limit	Control Parameters	Basis
Proteinase K	Not available	Not available	USA. Occupational Exposure Limits (OSHA). Table Z-1 limits for air contaminants. None

8.2 Engineering measures

Ensure adequate ventilation, especially in confined areas. Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of the workday.

8.3 Personal protective equipment (PPE)

Personal protective equipment requirement is dependent on the user institution's risk assessment and are specific to the risk assessment for each laboratory where this material may be used.

Respiratory protection

In case of insufficient ventilation, wear suitable respiratory equipment. Not required under normal conditions of use.

Hand protection

Impervious gloves

Eye protection

Safety glasses with side shields

Skin and body protection

Wear suitable protective clothing.

Hygiene measures

Handle in accordance with good industrial hygiene and safety practice. Wash hands after using.

8.4 Environmental Exposure Controls

None.

SECTION 9. Physical and chemical properties

9.1 General Information

Form:	Solid
Color:	Brown
Odor:	odorless
Odor Threshold:	Not determined
pH Value at 20°C (68°F):	Not determined



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Melting point/melting range:	Not determined
Freezing point:	Not determined
Boiling point/boiling range:	Not determined
Flash point:	Not applicable
Flammability (solid, gaseous):	Not applicable
Evaporation rate:	Not determined
Auto-igniting:	Product is not self-igniting
Danger of explosion:	Product does not present an explosion hazard
Explosion limits:	
Lower	Not determined
Upper	Not determined
Density at 20°C:	Not determined
Vapor Pressure:	Not determined
Vapor Density:	Not determined
Partition coefficient: n-octanol/water:	Not determined
Decomposition Temperature:	Not determined
Viscosity:	Not determined
Solubility in/Miscibility with:	
Water	Not determined
Dynamic	Not determined

9.2 Other information:

No additional information available.

SECTION 10: Stability and reactivity

Reactivity

No dangerous reaction known under conditions of normal use..

Chemical stability

Stable under normal conditions.

Possibility of hazardous reactions

No data available.

Conditions to avoid

No data available.

Incompatible materials

No data available.

Hazardous decomposition products

No data available.



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SECTION 11: Toxicological Information

Information on toxicological effects

Chemical name	LD50 (oral, rat/mouse)	LD50 (dermal, rat/rabbit)	LC50 (inhalation, rat/mouse)
Proteinase K	No data available	No data available	No data available

Acute toxicity

No data available.

Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/eye irradiation

Causes serious eye damage.

Respiratory or skin sensitization

May be harmful if inhaled and may cause skin sensitization.

Germ cell mutagenicity

No data available.

Carcinogenicity

No data available.

Reproductive toxicity

No data available.

Specific target organ toxicity-single exposure

Lung irritant, lung sensitizer.

SECTION 12: Ecological Information

Ecotoxicity Effects	No information available.
Acute Aquatic Toxicity	No information available.
Chronic aquatic Toxicity	Not classified chronic.
Mobility in Soil	No information available.
Biodegradation	No information available.
Bioaccumulation	Does not bioaccumulate.

SECTION 13: Disposal considerations

Waste Treatment Methods

Dispose of in accordance with all Local, State, Federal and International Regulations.



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SECTION 14: Transport information

IATA

Proper shipping name	Not classified as dangerous to transport.
UN-No	None
Transport Hazard class(es)	None
Subsidiary class	None
Packing group	None

SECTION 15: Regulatory information

United States

SARA Section 311/312 (Specific toxic chemical listings)

None of the ingredients listed.

SARA Section 313 (Specific toxic chemical listings)

None of the ingredients listed.

RCRA (hazardous waste code)

None of the ingredients listed.

TSCA (Toxic Substances Control Act)

None of the ingredients listed.

CERCLA (Comprehensive Environmental Response, Compensation and Liability Act)

None of the ingredients listed.

Proposition 65 (California)

Chemicals known to cause cancer

None of the ingredients listed.

Chemicals known to cause reproductive toxicity for females

None of the ingredients listed.

Chemicals known to cause reproductive toxicity for males

None of the ingredients listed.

Chemicals known to cause developmental toxicity

None of the ingredients listed.



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Canada

Canadian Domestic Substances List (DSL)

None of the ingredients listed.

Canadian NPRI Ingredient Disclosure list (limit 0.1%)

None of the ingredients listed.

WHMIS Hazard Class

D2B Toxic Materials



This product has been classified according to the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.

Europe

Candidate substances for authorization under the Regulation (EC) No 1907/2006 (REACH)

Not applicable.

Substances included in Annex XIV of REACH ("Authorization List") and sunset date

Not applicable.

Regulation (EC) No 1005/2009, about substances that deplete the ozone layer

Not applicable.

Article 95, REGULATION (EU) No 528/2012

Not applicable.

REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products

Not applicable.

Limitations to commercialization and the use of certain dangerous substances and mixtures (Annex XVII REACH, etc.)

Not applicable.

SECTION 16: Other information

Disclaimer/Statement of Liability

The Safety Data Sheet (SDS) contains all information as required by the Hazard Communication Standard and the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be



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unfamiliar, we do not assume any responsibility for the results of its use and all persons received it must make their own determination of the effects, properties, protections and disposal which pertain to their particular conditions. The responsibility to provide a safe workplace remains with the user who should consider the health hazards and safety information contained in this document as a guide. The user should take the precautions required. Caution should be used in the handling and use of the material. No representation, warranty, or guarantee, express or implied including a warranty of fitness or merchantability for a particular purpose is constituted by the information in this SDS.